INTERNATIONAL STANDARD

ISO 80601-2-74

First edition
2017-05

Medical electrical equipment —

Part 2-74:
Particular requirements for basic safety and essential performance of respiratory humidifying equipment

Appareils électromédicaux —

Partie 2-74: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'humidification respiratoire

Reference number
ISO 80601-2-74:2017(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*.

This first edition of ISO 80601-2-74 cancels and replaces the third edition of ISO 8185:2007[1], which has been technically revised. It also incorporates the third edition of IEC 60601-1, including amendment 1, the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, including amendment 1, the second edition of IEC 60601-1-8, including amendment 1, and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

— extending the scope to include the HUMIDIFIER and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the HUMIDIFIER, and thus not only the HUMIDIFIER itself;

— identification of ESSENTIAL PERFORMANCE for a HUMIDIFIER and its ACCESSORIES;

— modification of the humidification test PROCEDURE and the disclosure of humidification performance;

— more fully dimensioning the removable temperature sensor port and sensor;

— removal of requirements for so-called "bubble" HUMIDIFIERS as a separate document is being prepared for them[8];

and the following additions:

— requirements for mechanical strength (via IEC 60601-1-11);

— new symbols;

— requirements for a HUMIDIFIER as a component of an ME SYSTEM;

— requirements for ENCLOSURE integrity (water ingress via IEC 60601-1-11);

— requirements for cleaning and disinfection PROCEDURES (via IEC 60601-1-11);

— requirements for BIOCOMPATIBILITY;

— requirements for USABILITY.

Introduction

This document specifies requirements for respiratory humidifying equipment intended for use on PATIENTS in HOME HEALTHCARE ENVIRONMENT and in healthcare facilities. HUMIDIFIERS are used to raise the water content of gases delivered to PATIENTS. Gases available for medical use do not contain sufficient moisture and can damage or irritate the respiratory tract or desiccate secretions of PATIENTS whose upper airways have been bypassed. Inadequate humidity at the PATIENT-CONNECTION PORT can cause drying of the upper airway, or desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, which can cause narrowing or even obstruction of the airway[19][20]. Heat is employed to increase the water output of the HUMIDIFIER.

In addition, many HUMIDIFIERS utilize heated BREATHING TUBES in order to increase operating efficiency and reduce water loss (condensate) as well as heat loss in the BREATHING TUBE. Ventilator and anaesthesia BREATHING TUBES in common use might not withstand the heat generated by HUMIDIFIERS and BREATHING TUBE heating mechanisms.

Many HUMIDIFIER MANUFACTURERS use off-the-shelf electrical connectors for their electrically heated BREATHING TUBES. However, since different MANUFACTURERS have used the same electrical connector for different power outputs, electrically heated BREATHING TUBES can be physically, but not electrically, interchangeable. Use of improper electrically heated BREATHING TUBES has caused overheating, circuit melting, PATIENT and OPERATOR burns and fires. It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between HUMIDIFIERS and BREATHING TUBES produced by different MANUFACTURERS.

Since the safe use of a HUMIDIFIER depends on the interaction of the HUMIDIFIER with its many ACCESSORIES, this document sets total system performance requirements up to the PATIENT-CONNECTION PORT. These requirements are applicable to ACCESSORIES such as BREATHING TUBES (both heated and non-heated), temperature sensors and equipment intended to control the environment within these BREATHING TUBES.

Humidification can also be used by respiratory support ME EQUIPMENT to increase PATIENT comfort and compliance with the therapy. Examples are obstructive sleep apnoea and nasal high flow therapy equipment. The HUMIDIFICATION OUTPUT requirements of such ME EQUIPMENT is less demanding as the PATIENT'S upper airway is not bypassed.

HUMIDIFIERS are commonly used with air and air-oxygen mixtures and any HUMIDIFIER should be able to operate with these gases. Care should be taken if using other gas mixes such as helium-oxygen mixtures, as the different physical and thermal properties of these gases may disturb the operation of the HUMIDIFIER.

In this document, the following print types are used:

— Requirements and definitions: roman type;

— *Test specifications: italic type*;

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— Terms defined in CLAUSE 3 of the general standard, in this document or as noted: small capitals;

In referring to the structure of this document, the term

— "clause" means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Medical electrical equipment —

Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

201.1 Scope, object and related standards

IEC 60601-1:2005+AMD1:2012, Clause 1 applies, except as follows.

201.1.1 * Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a HUMIDIFIER, also hereafter referred to as ME EQUIPMENT, in combination with its ACCESSORIES, the combination also hereafter referred to as ME SYSTEM.

This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to a HUMIDIFIER where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the HUMIDIFIER.

EXAMPLE 1 Heated BREATHING TUBES (heated-wire BREATHING TUBES) or ME EQUIPMENT intended to control these heated BREATHING TUBES (heated BREATHING TUBE controllers).

NOTE 1 Heated BREATHING TUBES and their controllers are ME EQUIPMENT and are subject to the requirements of IEC 60601-1.

NOTE 2 ISO 5367 specifies other safety and performance requirements for BREATHING TUBES.

This document includes requirements for the different medical uses of humidification, such as invasive ventilation, non-invasive ventilation, nasal high-flow therapy, and obstructive sleep apnoea therapy, as well as humidification therapy for tracheostomy PATIENTS.

NOTE 3 A HUMIDIFIER can be integrated into other equipment. When this is the case, the requirements of the other equipment also apply to the HUMIDIFIER.

EXAMPLE 2 Heated HUMIDIFIER incorporated into a critical care ventilator where ISO 80601-2-12[12] also applies.

EXAMPLE 3 Heated HUMIDIFIER incorporated into a homecare ventilator for dependent PATIENTS where ISO 80601-2-72[14] also applies.

EXAMPLE 4 Heated HUMIDIFIER incorporated into sleep apnoea therapy equipment where ISO 80601-2-70[13] also applies.

This document also includes requirements for an ACTIVE HME (HEAT AND MOISTURE EXCHANGER), ME EQUIPMENT which actively adds heat and moisture to increase the humidity level of the gas delivered from the HME to the PATIENT. This document is not applicable to a passive HME, which returns a portion of the expired moisture and heat of the PATIENT to the respiratory tract during inspiration without adding heat or moisture.

NOTE 4 ISO 9360-1[5] and ISO 9360-2[6] specify the safety and performance requirements for a passive HME.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

NOTE 5 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document does not specify the requirements for cold pass-over or cold bubble-through humidification devices, the requirements for which are given in ISO 20789:—.[8]

This document is not applicable to equipment commonly referred to as "room humidifiers" or humidifiers used in heating, ventilation and air conditioning systems, or HUMIDIFIERS incorporated into infant incubators.

This document is not applicable to nebulizers used for the delivery of drugs to PATIENTS.

NOTE 6 ISO 27427[10] specifies the safety and performance requirements for nebulizers.

This document is a particular standard in the IEC 60601-1 and the ISO/IEC 80601 series.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for a HUMIDIFIER, as defined in 201.3.209, and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the HUMIDIFIER and the ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of a HUMIDIFIER.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard[1] and Clause 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 and IEC 60601-1-11 apply as modified in Clauses 202, 206, 208 and 211, respectively. IEC 60601-1-3[15] does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular

1 The general standard is IEC 60601-1:2005+AMD1:2012.

ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.6 in this document addresses the content of Clause 6 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 6060-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005+AMD1:2012, Clause 2 applies, except as follows.

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010+AMD1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

IEC 60601-1-8:2006+AMD1:2012, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 18562-1:—[2], *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-2-19:2009, *Medical electrical equipment — Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators*

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[2] To be published.

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*

EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001[1], ISO 7396-1:2016, ISO 9360-1:2000[5], ISO 23328-2:2002[9], IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-11:2015, IEC 62366-1:2015[18] and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An alphabetized index of defined terms is found beginning in Annex DD.

IEC 60601-1:2005+AMD1:2012, Clause 3 applies, except as follows:

Additions:

201.3.201
ACTIVE HME
ACTIVE HEAT AND MOISTURE EXCHANGER
HUMIDIFIER where water, water vapour or heat is actively added to the HEAT AND MOISTURE EXCHANGER (HME) to increase the humidity level of the gas flowing from the HME to the PATIENT

201.3.202
AIRWAY PRESSURE
P_{aw}
pressure at the patient-connection port

201.3.203
BODY TEMPERATURE PRESSURE, SATURATED
BTPS
ambient atmospheric pressure and a RELATIVE HUMIDITY of 100 % at a temperature of 37 °C

Note 1 to entry: Respiratory physiology lung volumes and flows are standardized to BTPS.

201.3.204
DELIVERED GAS TEMPERATURE
temperature of the gas, or aerosol, or both, at the PATIENT-CONNECTION PORT

201.3.205
FLOW-DIRECTION-SENSITIVE COMPONENT
component or ACCESSORY through which gas flow has to be in one direction only for proper functioning or PATIENT safety

[SOURCE: ISO 4135:2001, 3.1.7[1], modified — added "or ACCESSORY" and replaced "must" with "has to".]

201.3.206
HEATED BREATHING TUBE CONTROLLER
ME EQUIPMENT which controls the temperature or the heating of a BREATHING TUBE

Note 1 to entry: A HEATED BREATHING TUBE CONTROLLER can be either stand-alone or part of the HUMIDIFIER.

201.3.207
HUMIDIFICATION CHAMBER
part of the HUMIDIFIER in which vaporization or nebulization takes place

201.3.208
HUMIDIFICATION OUTPUT
total mass of water vapour per unit volume of gas at the PATIENT-CONNECTION PORT under BTPS conditions

201.3.209
HUMIDIFIER
ME EQUIPMENT that adds water in the form of droplets or vapour, or both, to the inspired gas

EXAMPLE Vaporizing and ultrasonic equipment and an ACTIVE HME are types of HUMIDIFIERS.

201.3.210
LIQUID CONTAINER
part of the HUMIDIFIER which holds the liquid

Note 1 to entry: The LIQUID CONTAINER can be accessible to the breathing gas.

Note 2 to entry: The LIQUID CONTAINER can also be part of the HUMIDIFICATION CHAMBER.

Note 3 to entry: The LIQUID CONTAINER can be detachable for filling.

201.3.211
LIQUID RESERVOIR
part of the HUMIDIFIER which replenishes the LIQUID CONTAINER

201.3.212
MAXIMUM LIMITED PRESSURE
$P_{\mathrm{LIM\ max}}$
highest AIRWAY PRESSURE during NORMAL USE or under SINGLE FAULT CONDITION

201.3.213
MAXIMUM OPERATING PRESSURE
maximum pressure in the HUMIDIFICATION CHAMBER during NORMAL USE

201.3.214
MEASURED GAS TEMPERATURE
temperature of the gas, or aerosol, or both, that the ME SYSTEM is measuring and, if applicable, displaying

201.3.215
MONITORING EQUIPMENT
ME EQUIPMENT or part that continuously or continually measures and indicates the value of a variable to the OPERATOR

[SOURCE: ISO 80601-2-12:2011, 201.3.217[12]]

201.3.216
PATIENT-CONNECTION PORT
port at the PATIENT-end of the BREATHING TUBES intended for connection to an airway device

EXAMPLE A tracheal tube, tracheostomy tube, face mask and supralaryngeal airway are all airway devices.

201.3.217
PROTECTION DEVICE
part or function of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

[SOURCE: ISO 60601-2-12:2011, 201.3.220[12]]

201.3.218
RELATIVE HUMIDITY
water vapour pressure, expressed as a percentage of the saturation vapour pressure, at a particular temperature

201.3.219
SET TEMPERATURE
temperature at which the HUMIDIFIER attempts to maintain MEASURED GAS TEMPERATURE

Note 1 to entry: The SET TEMPERATURE may be OPERATOR-adjustable.

201.3.220
STANDARD TEMPERATURE AND PRESSURE, DRY
STPD
pressure of 101,325 kPa at an operating temperature of 20 °C

201.3.221
VALIDATION
confirmation, through the provision of OBJECTIVE EVIDENCE, that the requirements for a specific INTENDED USE or application have been fulfilled

Note 1 to entry: The OBJECTIVE EVIDENCE needed for a VALIDATION is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The term "VALIDATED" is used to designate the corresponding status.

Note 3 to entry: The use conditions for VALIDATION can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13[4]]

201.4 General requirements

IEC 60601-1:2005+AMD1:2012, Clause 4 applies, except as follows.

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005+AMD1:2012, 4.3 applies, except as follows.

Additional subclause:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
For category 1 HUMIDIFIERS, delivery of HUMIDIFICATION OUTPUT or generation of a TECHNICAL ALARM CONDITION	201.12.1.101[a]
For HUMIDIFIERS equipped with SET TEMPERATURE MONITORING EQUIPMENT, delivery of HUMIDIFICATION OUTPUT or generation of a TECHNICAL or PHYSIOLOGICAL ALARM CONDITION	201.12.1.101[a]
For all other category 2 HUMIDIFIERS for the purposes of this document, category 2 HUMIDIFIERS are considered to not have ESSENTIAL PERFORMANCE. Notwithstanding this fact, when this document refers to ESSENTIAL PERFORMANCE as acceptance criteria, the delivery of HUMIDIFICATION OUTPUT is evaluated.[a]	—

[a] Subclause 202.8.1.101 indicates methods of evaluating delivery of HUMIDIFICATION OUTPUT as acceptance criteria following specific tests required by this document.

201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Amendment (add at end of 4.6 prior to the compliance check):

aa) The GAS PATHWAYS shall be subject to the requirements for APPLIED PARTS according to this subclause.

bb) The HUMIDIFIER or its parts or ACCESSORIES that can come into contact with the PATIENT shall be subject to the requirements for APPLIED PARTS according to this subclause.

NOTE For the purposes of this document, GAS PATHWAYS are considered to be any part or surface that can be exposed to the PATIENT respiratory gas.

Additional subclauses:

201.4.11.101 * Additional requirements for pressurized gas input

201.4.11.101.1 Overpressure requirement

a) If the HUMIDIFIER is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1:2016, then it:

   1) shall operate and meet the requirements of this document throughout its RATED range of input pressure;

   2) shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of 1 000 kPa.

   NOTE 1 An internal pressure regulator can be required to accommodate the SINGLE FAULT CONDITION of maximum input pressure, as well as the RATED range of input pressure.

NOTE 2 Under the SINGLE FAULT CONDITION of overpressure, it is desirable for gas to continue to flow to the BREATHING SYSTEM. Under this condition, the flowrate from the HUMIDIFIER is likely to be outside of its specification.

b) If the HUMIDIFIER has a maximum RATED input pressure in excess of 600 kPa, the HUMIDIFIER shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of twice the maximum RATED input pressure.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings, by functional testing in SINGLE FAULT CONDITION and inspection of the RISK MANAGEMENT FILE.

201.4.11.101.2 Compatibility requirement

If the HUMIDIFIER is intended to be directly connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1:2016 then:

a) the RATED range of input pressure shall cover the range specified in ISO 7396-1:2016;

b) under NORMAL CONDITION,

   1) the maximum 10 s average input flowrate required by the HUMIDIFIER for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the gas input port, and

   2) the transient input flowrate shall not exceed 200 l/min averaged for 3 s.

   or:

   3) the ACCOMPANYING DOCUMENTS shall disclose:

      i) the maximum 10 s average input flowrate required by the HUMIDIFIER for each gas at a pressure of 280 kPa, measured at the gas input port;

      ii) the maximum transient input flowrate averaged for 3 s required by the HUMIDIFIER for each gas at a pressure of 280 kPa, measured at the gas input port;

      iii) a warning to the effect that this HUMIDIFIER is a high flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the RISK that the HUMIDIFIER interferes with the operation of adjacent equipment.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings and by inspection of the ACCOMPANYING DOCUMENTS.

EXAMPLE Highest driving gas consumption, highest gas delivery and, if provided, the highest RATED gas consumption at any gas power supply output.

201.4.101 Additional general requirements

HUMIDIFIERS are frequently used in combination with other respiratory ME EQUIPMENT or medical devices. The BASIC SAFETY and ESSENTIAL PERFORMANCE of both the HUMIDIFIER and the other respiratory ME EQUIPMENT or medical device are interdependent.

a) Where a HUMIDIFIER is intended to be used in combination with other respiratory ME EQUIPMENT or medical devices as indicated in its instructions for use, it shall be evaluated in combination with the other respiratory ME EQUIPMENT or medical devices when applying the requirements of this document.

b) As appropriate, the requirements of the particular standards of the other respiratory ME EQUIPMENT or medical devices indicated in the instructions for use of the HUMIDIFIER shall also apply to the combination of the HUMIDIFIER and other respiratory ME EQUIPMENT or medical devices.

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 5 applies, except as follows.

201.5.4 Other conditions

Amendment (add to the list):

aa) Unless otherwise specified, the LIQUID CONTAINER and LIQUID RESERVOIR, if provided, shall be filled to maximum capacity, as indicated in the instructions for use, at the beginning of a test with distilled water at the ambient test temperature.

bb) For the purpose of checking compliance with requirements of this document, the DELIVERED GAS TEMPERATURE shall be sensed in the BREATHING TUBE not more than 50 mm from the PATIENT-CONNECTION PORT (see Annex BB).

Additional subclauses:

201.5.101 Additional requirements for general requirements for testing of ME EQUIPMENT

201.5.101.1 Humidifier test conditions

a) For testing, the HUMIDIFIER:

1) shall be connected to gas supplies as specified for NORMAL USE, except that industrial grade oxygen; and

2) air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

c) The moisture content of all gas supplies shall be less than 1 mg/l.

201.5.101.2 * Gas flowrate and leakage specifications

In this document, requirements for the flowrate, volume and leakage are expressed at STANDARD TEMPERATURE AND PRESSURE, DRY (STPD), except for those associated with the BREATHING SYSTEM, which are expressed at BODY TEMPERATURE AND PRESSURE, SATURATED (BTPS).

Correct all test measurements to STPD or BTPS, as appropriate.

201.5.101.3 * HUMIDIFIER testing errors

a) For the purposes of this document, declared tolerances shall be adjusted by the measurement uncertainty.

b) The MANUFACTURER shall disclose the measurement uncertainty of each disclosed tolerance in the technical description.

Check compliance by inspection of the instructions for use and the technical description.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 6 applies, except as follows.

Additional subclause:

201.6.101 HUMIDIFIER classification

201.6.101.1 Category 1

A HUMIDIFIER intended for use in PATIENTS whose upper airways have been bypassed (invasive ventilation), shall be classified category 1.

NOTE A category 1 HUMIDIFIER can also be suitable for use in PATIENTS whose upper airways have not been bypassed.

201.6.101.2 Category 2

A HUMIDIFIER not intended for use in PATIENTS whose upper airways have been bypassed (i.e. intended for non-invasive ventilation, nasal high flow therapy, sleep apnoea CPAP treatment), shall be classified category 2.

201.6.101.3 Classification

a) A HUMIDIFIER shall be classified either as category 1 or category 2.

b) A particular HUMIDIFIER may be classified as category 1 over a certain specified range of flowrates and temperatures, but also as category 2 over a wider specified range of flowrates and temperatures.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005+AMD1:2012, Clause 7 applies, except as follows:

Additional subclause:

201.7.2.4.101 Additional requirements for ACCESSORIES

a) ACCESSORIES supplied separately shall

 1) fulfil the requirements of 201.7.2.101, 201.7.2.13.101 and 201.7.2.17.101, and

2) be marked with an indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the HUMIDIFIER, if applicable.

b) If marking the ACCESSORY is not practicable, this information may be placed in the instructions for use.

NOTE The MANUFACTURER of the ACCESSORY can be the HUMIDIFIER MANUFACTURER or another entity ("third-party manufacturer", healthcare provider or durable medical equipment provider) and all these entities are expected to ensure compliance with this requirement. Additional requirements are found in 201.102.

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for any limitations or adverse effects of the ACCESSORY.

201.7.2.5 ME EQUIPMENT intended to receive power from other equipment

Amendment (add before the last paragraph):

NOTE For a heated BREATHING TUBE, the connector to the HUMIDIFIER or HEATED BREATHING TUBE CONTROLLER is a connection to the supply that might need this marking.

201.7.2.8.2 * Other power sources

Amendment (add at the end of the subclause):

NOTE The connector on the HUMIDIFIER or HEATED BREATHING TUBE CONTROLLER for a heated BREATHING TUBE is a connector that might need this marking.

Additional subclauses:

201.7.2.13.101 Additional requirements for physiological effects

a) Any natural rubber latex-containing components in the GAS PATHWAYS or ACCESSORIES shall be marked as containing latex.

b) Such marking shall be CLEARLY LEGIBLE.

c) Symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.1.101, symbol 4) may be used.

d) The instructions for use shall disclose any natural rubber latex-containing components.

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

a) The marking on packages shall be CLEARLY LEGIBLE and shall include

1) a description of the contents,

2) an identification reference to the batch, type or serial number or symbols 5.1.5, 5.1.6 or 5.1.7 from ISO 15223-1:2016 (Table 201.D.1.101, symbol 1, symbol 2 or symbol 3), and

3) for packages containing natural rubber latex, the word "LATEX", or symbol 5.4.5 from ISO 15223-1:2016 (Table 201.D.1.101, symbol 4).

b) For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent for the MODEL OR TYPE REFERENCE.

Check compliance by inspection.

201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

a) The marking of ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

   1) the maximum and minimum liquid levels, if these are necessary to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE of the HUMIDIFIER.

b) If applicable, marking of OPERATOR-accessible ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

   2) the special storage, handling or operating instructions;

   3) the particular warnings and/or precautions relevant to the immediate operation of the HUMIDIFIER;

   4) an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a TOOL;

   5) if a pressure-relief PROTECTION DEVICE is provided, the pressure at which it opens. This marking shall be on or near the pressure-relief PROTECTION DEVICE.

Check compliance by inspection.

201.7.4.3 * Units of measurement

IEC 60601-1:2005+AMD1:2012, 7.4.3 applies, except as follows:

Amendment (add to the bottom as a new row in Table 1):

aa) All gas volume, flowrate and leakage specifications

   100) shall be expressed at stpd (standard temperature and pressure, dry),

   101) except those associated with the BREATHING SYSTEM which shall be expressed at BTPS (BODY TEMPERATURE AND PRESSURE, SATURATED).

201.7.9.1 Additional general requirements

IEC 60601-1:2005+AMD1:2012, 7.9.1 applies, except as follows:

Amendment (replace the first dash with):

— Name or trade name and address of:

   — the manufacturer;

   — where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

   to which the RESPONSIBLE ORGANIZATION can refer;

201.7.9.2 Instructions for use

IEC 60601-1:2005+AMD1:2012, 7.9.2 applies, except as follows:

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

a) For a HUMIDIFIER intended for use in the HOME HEALTHCARE ENVIRONMENT, separate instructions for use shall be provided for:

1) the LAY OPERATOR;

2) the supervising clinician or the healthcare professional OPERATOR.

b) The MANUFACTURER may choose in which instructions for use to place the information required by this document unless otherwise indicated in this document based on RISK MANAGEMENT and USABILITY considerations.

c) The supervising clinician or the healthcare professional OPERATOR instructions for use shall include the information contained in the LAY OPERATOR instructions for use.

Check compliance by inspection of the instructions for use, the RISK MANAGEMENT FILE and USABILITY ENGINEERING FILE.

201.7.9.2.1.102 Additional general requirements

The instructions for use shall include:

a) if the HUMIDIFIER, its parts or ACCESSORIES are intended for single use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the HUMIDIFIER, its parts or ACCESSORIES were reused;

b) if the HUMIDIFIER, its parts or ACCESSORIES are intended for single use, that it is single use and information regarding the intended duration of use;

c) a statement on the quality and purity of the water to be used in the HUMIDIFIER, and that adding other substances can have adverse effects.

NOTE A nebulizer, located between the ventilator and the gas inlet port of the HUMIDIFICATION CHAMBER is a source of such substances.

Check compliance by inspection.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

The instructions for use shall include:

a) * a warning statement to the effect that "WARNING: Do not add any attachments or accessories to the humidifier that are not listed in the instruction for use of the humidifier or accessory or the humidifier might not function correctly affecting the quality of the therapy or injuring the patient."

b) a warning statement to the effect that "WARNING: Do not use the humidifier at an altitude above [insert maximum RATED altitude] or outside a temperature of [insert RATED temperature range]. Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient."

c) a warning statement to the effect that "WARNING: To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used".

d) if applicable, a warning statement to the effect that "WARNING: Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient."

Check compliance by inspection of the instructions for use.

201.7.9.2.6 Installation

Amendment (add at the end of the subclause):

The instructions for use shall give recommended mounting methods and other relevant information for installation of the HUMIDIFIER.

Additional subclauses:

201.7.9.2.8.101 * Additional requirements for start-up PROCEDURE

NOTE For the purposes of this document, a start-up PROCEDURE is a pre-use test that is used to determine whether the HUMIDIFIER is ready for use.

a) If the HUMIDIFIER is equipped with an ALARM SYSTEM, then the instructions for use for the LAY OPERATOR shall disclose a method by which the ALARM SIGNALS can be functionally tested to determine if they are operating correctly.

b) Portions of this test method may be performed automatically by the HUMIDIFIER or may require OPERATOR action.

EXAMPLE 1 Combination of the power-on self-test routines and OPERATOR actions that functionally check the ALARM SIGNALS.

c) The specifications of any required ACCESSORIES or test equipment needed to perform these tests shall be disclosed in the instructions for use.

EXAMPLE 2 A test temperature probe that activates the ALARM CONDITION.

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101 Additional requirements for operating instructions

201.7.9.2.9.101.1 LAY OPERATOR operating instructions

The instructions for use for the LAY OPERATOR shall include:

a) the conditions under which the HUMIDIFIER maintains the accuracy of controlled and displayed variables as disclosed in the instructions for use;

EXAMPLE 1 Acceptable range of water level.

EXAMPLE 2 Interval of calibration of a sensor.

b) an explanation of the meaning of the IP classification marked on the ME EQUIPMENT;

c) the maximum volume of water, expressed in ml, available for vaporization contained in the LIQUID CONTAINER and, if provided, in the LIQUID RESERVOIR;

d) an indication of the expected duration of operation between refills, under specified operating conditions;

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101.2 * Supervising clinician operating instructions

The instructions for use intended for the supervising clinician or the healthcare professional OPERATOR shall include:

a) the MAXIMUM LIMITED PRESSURE of the HUMIDIFIER and ACCESSORIES;

b) the MAXIMUM OPERATING PRESSURE;

c) the RATED range of environmental operating conditions (temperature and altitude) of NORMAL USE;

d) the maximum DELIVERED GAS TEMPERATURE, if the HUMIDIFIER is not provided with a means of continuously indicating the MEASURED GAS TEMPERATURE;

e) * the location in the HUMIDIFIER or ACCESSORIES to which the displayed MEASURED GAS TEMPERATURE is referenced;

f) the gas leakage of the HUMIDIFIER or individual components, as appropriate, at the maximum RATED pressure. The gas leakage should be determined in accordance with ISO 5367 or an equivalent method. The gas leakage for an ACTIVE HME should be determined in accordance with ISO 9360-1[5] or ISO 9360-2[6];

g) * unless the HUMIDIFIER is integrated into other equipment,

   1) the RATED range of the following characteristics of the assembled OPERATOR-detachable parts, over which the accuracies of set and monitored humidification are maintained:

      i) flowrate;

      ii) GAS PATHWAY resistance;

      iii) GAS PATHWAY compliance.

   2) These specifications may be presented in ranges.

   3) The accuracies of set and monitored values may be presented as a function of these characteristics.

4) Since these values can be affected by the depletion of the liquid, the minimum and maximum values shall be disclosed.

5) Compliance and resistance can be nonlinear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min, maximum flowrate and the maximum RATED pressure).

6) The resistance and compliance should be determined in accordance with ISO 5367 or an equivalent method.

7) The resistance and compliance for an ACTIVE HME should be determined in accordance with ISO 9360-1[5] or ISO 9360-2[6].

h) * unless the HUMIDIFIER is integrated into other equipment, the pressure drop, as a function of flowrate, across the HUMIDIFIER and ACCESSORIES or individual components.

8) The pressure drop should be determined in accordance with ISO 5367 or an equivalent method.

9) The pressure drop for an ACTIVE HME should be determined in accordance with ISO 9360-1[5] or ISO 9360-2[6].

i) the known adverse effects on the performance of the HUMIDIFIER when exposed to, for example, electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transient magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference.

If applicable, instructions for use shall disclose

j) the essential technical characteristics of each recommended BREATHING SYSTEM FILTER;

EXAMPLE Deadspace and resistance.

k) * for a HUMIDIFIER that entrains air for the purpose of diluting oxygen:

10) a statement to the effect that the oxygen concentration can be affected by a partial obstruction downstream of the HUMIDIFIER, e.g. when using ACCESSORY equipment;

11) a recommendation that the oxygen concentration be measured at the point of delivery to the PATIENT.

Check compliance by inspection of the instructions for use.

201.7.9.2.12 Cleaning, disinfection and sterilization

IEC 60601-1:2005+AMD1:2012, 7.9.2.12 applies, except as follows.

Amendment (add after NORMAL USE):

and SINGLE FAULT CONDITION

Amendment (replace the second bullet):

aa) List the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT, parts or ACCESSORIES can tolerate.

bb) Alternatively, another method to determine reduced performance and the end of useful life may be provided.

Amendment (add after bulleted list):

cc) The instructions for use shall identify the portions of the GAS PATHWAYS through the HUMIDIFIER that can become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.

Additional subclauses:

201.7.9.2.13.101 Additional requirements for maintenance

The instructions for use shall disclose

a) a description of periodic visual safety inspections that should be performed by the OPERATOR, and

b) if applicable, the INTERNAL ELECTRICAL POWER SOURCE care and maintenance PROCEDURES, including instructions for recharging or replacement.

Check compliance by inspection of the instructions for use.

201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material

The instructions for use of a HUMIDIFIER shall identify

a) at least one set of ACCESSORIES, and

b) if applicable, the ME EQUIPMENT necessary for the HUMIDIFIER'S INTENDED USE.

If applicable, the instructions for use shall disclose

c) any restrictions on the positioning of components within the BREATHING SYSTEM, and

EXAMPLE Where such components are FLOW-DIRECTION-SENSITIVE COMPONENTS.

d) any adverse effect of any recommended ACCESSORY on the ESSENTIAL PERFORMANCE or BASIC SAFETY of the HUMIDIFIER or equipment to which it is connected.

Check compliance by inspection of the instructions for use and inspection of the RISK MANAGEMENT FILE for any adverse effect of any recommended ACCESSORY.

201.7.9.3.1.101 Additional general requirements

The technical description shall disclose

a) the interdependence of control functions, and

b) a statement to the effect that the responsible organization should ensure the compatibility of the humidifier and all of the parts and accessories used to connect to the patient or other equipment before use.

Check compliance by inspection of the technical description.

201.7.9.3.101 Additional requirements for the technical description

a) The technical description shall disclose a description of a method for checking the function of the ALARM SYSTEM for each of the ALARM CONDITIONS specified in this document, if not performed automatically during start-up.

b) The technical description shall disclose which checks are performed automatically.

Check compliance by inspection of the technical description.

201.8 Protection against electrical HAZARDS form ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 8 applies, except as follows.

Additional subclause:

201.8.3.101 Additional requirements for classification of APPLIED PARTS

The APPLIED PARTS of a HUMIDIFIER and its ACCESSORIES shall be F-TYPE APPLIED PARTS.

Check compliance by inspection.

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Replacement:

e) Assemble the HUMIDIFIER to the BREATHING TUBE and other necessary ACCESSORIES. Wrap the metal foil around the PATIENT-CONNECTION PORT as mentioned under 8.7.4.6. The metal foil is considered as the only PATIENT CONNECTION for the APPLIED PART concerned.

201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 9 applies, except as follows.

Additional subclauses:

201.9.4.3.101 * Additional requirements for instability from unwanted lateral movement

a) A TRANSIT-OPERABLE HUMIDIFIER intended for use in either the HOME HEALTHCARE ENVIRONMENT or EMERGENCY MEDICAL SERVICES ENVIRONMENT shall include a means by which the HUMIDIFIER can be easily attached without the use of a TOOL to prevent unwanted movement during transport while in use.

b) The means shall hold the HUMIDIFIER to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward) and 1,0 g transverse (left, right) for at least 5 s each.

c) No more liquid than is specified in 201.13.1.101 shall exit the HUMIDIFICATION CHAMBER outlet from these accelerations or decelerations.

EXAMPLE Means to be physically restrained during transport in a personal vehicle, in an ambulance or on a wheelchair.

Check compliance by functional testing and the testing of 201.13.1.101.

201.9.6.2.1.101 Additional requirements for audible acoustic energy

The A-weighted sound pressure level emitted by the HUMIDIFIER shall be less than 50 dB as determined by the test method of this document.

Check compliance with the following test.

a) *Place the HUMIDIFIER on the sound-reflecting plane, fill the HUMIDIFICATION CHAMBER to the least favourable level and attach the least favourable set of ACCESSORIES from those indicated in the instructions for use.*

  — *Connect a ventilator or other appropriate flow source to the input of the HUMIDIFIER.*

  — *Acoustically isolate the test lung, if used, and flow source by a suitable means so that any noise caused by the test lung and flow source does not interfere with the sound measurement of the HUMIDIFIER.*

b) *If the flow source is a ventilator,*

  — *set the ventilator to volume control mode that generates ventilation as indicated in Table 201.102,*

  — *configure the test lung with the compliance and resistance components whose values are indicated in Table 201.102, and*

  — *connect the PATIENT-CONNECTION PORT to the test lung.*

c) *Otherwise, configure the flow source to worst case flow.*

d) *Using a microphone of the sound level meter complying with the requirements of class 1 specified in IEC 61672-1:2013 with frequency-weighting characteristic A and the time-weighting characteristic F as specified in ISO 3744:2010, measure the sound pressure levels in accordance with ISO 3744:2010, 8.2.1, at 10 positions in a hemisphere with a radius of 1 m from the geometric centre of the HUMIDIFIER in a free field over a reflecting plane as specified in ISO 3744:2010, 7.2.3 and 8.1.1. ISO 3744:2010, Annex F, shall not be utilized.*

e) *Confirm that the A-weighted background level of extraneous noise is at least 6 dB below that measured during the test.*

f) *Calculate the A-weighted sound pressure level averaged over the measurement surface according to ISO 3744:2010, 8.2.4.*

g) *Confirm that the measured sound pressure level is less than 50 dB.*

201.9.6.2.1.102 Additional requirements for audible acoustic energy for use with an incubator

A HUMIDIFIER with the BREATHING TUBE and other necessary ACCESSORIES intended for use with an incubator shall comply with the sound pressure level requirements of IEC 60601-2-19:2009, 201.9.6.2.1.101.

Check compliance by application of the tests of IEC 60601-2-19:2009, 201.9.6.2.1.101.

Table 201.102 — Test conditions for acoustic tests

Adjustable parameter	Test condition		
	For a HUMIDIFIER intended to provide an inspired volume		
	$V_{insp} \geq 300$ ml	300 ml $\geq V_{insp} \geq 50$ ml	$V_{insp} \leq 50$ ml
Inspired volume, V_{insp}[a]	500 ml	150 ml	30 ml
Ventilatory frequency, f	10 min^{-1}	20 min^{-1}	30 min^{-1}
I:E ratio	1/2	1/2	1/2
PEEP[b]	5 hPa	5 hPa	5 hPa
Resistance, R[c][21][22][23]	5 hPa(l/s)$^{-1}$ ± 10 %	20 hPa(l/s)$^{-1}$ ± 10 %	50 hPa(l/s)$^{-1}$ ± 10 %
Isothermal Compliance, C[c]	50 ml hPa^{-1} ± 5 %	20 ml hPa^{-1} ± 5 %	1 ml hPa^{-1} ± 5 %

[a] V_{insp} is measured by means of a pressure sensor on the test lung, where $V_T = C \times P_{max}$.

[b] If the PEEP is adjustable.

[c] The accuracy for C and R applies over the ranges of the measured parameters.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005+AMD1:2012, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005+AMD1:2012, Clause 11 applies, except as follows.

201.11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT

Amendment:

Notwithstanding the requirements of IEC 60601-1:2005+AMD1:2012, 11.1.2.2, the allowable maximum temperature of the ACCESSIBLE PART surfaces of BREATHING TUBES within 25 cm of the PATIENT-CONNECTION PORT shall not exceed 44 °C.

201.11.6.2 * Overflow in ME EQUIPMENT

Replacement:

a) Liquid overflowing from the LIQUID CONTAINER or LIQUID RESERVOIR shall

   1) not wet any MEANS OF PROTECTION that is liable to be adversely affected by liquid, nor

   2) result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

b) No HAZARDOUS SITUATION (as specified in IEC 60601-1:2005+AMD1:2012, 13.1 or 201.13.1.101) or unacceptable RISK due to overflow shall be developed:

   1) if the LIQUID CONTAINER or LIQUID RESERVOIR is filled to its maximum capacity;

2) for a PORTABLE HUMIDIFIER (e.g. table top), if it is tilted through an angle of 10° from any position of NORMAL USE when operated under NORMAL CONDITION at the maximum flowrate of NORMAL USE;

3) for a MOBILE HUMIDIFIER (e.g. pole-mounted), if it is

i) tilted through an angle of 20° from any position of NORMAL USE, and

ii) moved over a threshold as described in IEC 60601-1:2005+AMD1:2012, 9.4.2.4.3, and

4) for an ACTIVE HME, in the least favourable orientation;

when operated under NORMAL CONDITION at the maximum flowrate of NORMAL USE.

Check compliance by the following:

c) *Fill the LIQUID CONTAINER and LIQUID RESERVOIR to the indicated maximum level. Operate the HUMIDIFIER at its maximum RATED flowrate.*

d) *PORTABLE ME EQUIPMENT is subsequently tilted through an angle of 10° in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE.*

e) *MOBILE ME EQUIPMENT is subsequently tilted through an angle of 20° in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE and is moved over a threshold as described in IEC 60601-1:2005+AMD1:2012, 9.4.2.4.3.*

f) *Return the HUMIDIFIER to normal orientation and subsequently refill the LIQUID CONTAINER to the maximum level then add a further quantity equal to 15 % of the capacity of the LIQUID CONTAINER, poured in steadily over a period of 1 min.*

g) *After these PROCEDURES, the HUMIDIFIER is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection).*

h) *In addition, confirm that there is no more liquid than is specified in 201.13.1.101 exits the HUMIDIFICATION CHAMBER outlet.*

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM

Amendment (add additional requirement as new first paragraph):

aa) GAS PATHWAYS through the HUMIDIFIER and its ACCESSORIES that can become contaminated with body fluids or expired gases during NORMAL CONDITION or SINGLE FAULT CONDITION that are not single use

1) shall be designed to allow for cleaning and disinfection or cleaning and sterilization (additional requirements are found in IEC 60601-1:2005+AMD1:2012, 11.6.7 and IEC 60601-1-11:2015, Clause 8).

2) Dismantling may be used.

Amendment (add additional requirement and replace the compliance test):

bb) HUMIDIFIER ENCLOSURES shall be designed to allow for surface cleaning and disinfection to reduce to acceptable levels the RISK of cross infection of the OPERATOR, other persons or next PATIENT.

cc) Instructions for processing and reprocessing the HUMIDIFIER and its ACCESSORIES shall

102) comply with ISO 17664:2004 and ISO 14937:2009, and

103) be disclosed in the instructions for use.

NOTE 1 ISO 14159 provides guidance for the design of ENCLOSURES.

Check compliance by inspection of the RISK MANAGEMENT FILE. When compliance with this document could be affected by the cleaning or the disinfecting of the HUMIDIFIER or its parts or ACCESSORIES, clean and disinfect them 10 times in accordance with the methods indicated in the instruction for use, including any cooling or drying period. After these PROCEDURES, confirm that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained. Confirm that the MANUFACTURER has evaluated the effects of multiple PROCESS cycles and the effectiveness of those cycles.

NOTE 2 Additional information regarding the order of test is found in 211.10.1.1.

201.11.6.7 Sterilization of ME EQUIPMENT or ME SYSTEM

Amendment (add note before compliance test):

NOTE Additional requirements are found in IEC 60601–1:2005+AMD1:2012, 11.6.6 and IEC 60601–1-11:2015, Clause 8.

201.11.7 BIOCOMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

Amendment (add after existing text prior to the compliance statement):

aa) The MANUFACTURER of a HUMIDIFIER, BREATHING SYSTEM, its parts and ACCESSORIES shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the leaching or leaking of substances into the GAS PATHWAY.

bb) The GAS PATHWAYS shall be evaluated for BIOCOMPATIBILITY according to ISO 18562-1:—.

cc) Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

dd) The ACCESSIBLE PARTS and GAS PATHWAYS of a HUMIDIFIER, BREATHING SYSTEM, its parts or ACCESSORIES that contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction shall be marked as containing phthalates on the device itself or on the packaging that it contains phthalates.

ee) The symbol of EN 15986:2011 (Table 201.D.2.101, symbol 5) may be used.

ff) If the INTENDED USE of a HUMIDIFIER, BREATHING SYSTEM, its parts or ACCESSORIES include treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these phthalates shall be included in the RISK MANAGEMENT FILE.

gg) The instructions for use of a HUMIDIFIER, BREATHING SYSTEM, its parts or ACCESSORIES that contain such phthalates shall contain

100) information on RESIDUAL RISKS for these PATIENT groups, and

101) if applicable, on appropriate precautionary measures.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+AMD1:2012, Clause 12 applies, except as follows.

201.12.1 Accuracy of controls and instruments

Amendment (add after existing sentence):

aa) The HUMIDIFIER may provide means to reduce the visibility of its controls and indicators either automatically or by the OPERATOR action.

bb) If provided, the HUMIDIFIER shall automatically resume normal visibility during an ALARM CONDITION.

Check compliance by functional testing and application of the tests of IEC 60601-1:2005+AMD1:2012, 7.1.2.

Additional subclauses:

201.12.1.101 * HUMIDIFICATION OUTPUT

a) Over the range of flowrates, settings, ambient temperature, and gas inlet temperature and humidity of NORMAL USE, the HUMIDIFICATION OUTPUT at the PATIENT-CONNECTION PORT shall not be less than:

   1) 33 mg/l for a category 1 HUMIDIFIER operating in a mode intended for a PATIENT whose upper airways have been bypassed (invasive ventilation).

b) Over the range of flowrates, ambient temperature, and gas inlet temperature and humidity of NORMAL USE, the HUMIDIFIER shall be capable of delivering a HUMIDIFICATION OUTPUT at the PATIENT-CONNECTION PORT of at least:

   2) 12 mg/l for a category 1 HUMIDIFIER operating in a a mode intended for a PATIENT whose upper airways have not been bypassed (non-invasive ventilation);

   3) 12 mg/l for a category 2 HUMIDIFIER.

c) The HUMIDIFICATION OUTPUT shall either be

   4) determined for each BREATHING SYSTEM configuration indicated in the instructions for use, or

   5) determined for the worst-case BREATHING SYSTEM configurations indicated in the instructions for use.

   NOTE The worst-case BREATHING SYSTEM configuration can be different for different flowrates and HUMIDIFICATION OUTPUT.

d) If worst-case BREATHING SYSTEM configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

e) The HUMIDIFICATION OUTPUT (in mg/l) over the RATED range of gas flowrates and settings shall be disclosed in the instructions for use.

Check compliance by inspection of the instructions for use and RISK MANAGEMENT FILE for the rationale, if applicable, and with the tests of Annex C.

201.12.1.102 * SET TEMPERATURE accuracy and MONITORING EQUIPMENT

a) A HUMIDIFIER shall be equipped with an ALARM SYSTEM that includes:

1) at least a MEDIUM PRIORITY ALARM CONDITION for a category 1 HUMIDIFIER; or

2) if equipped with SET TEMPERATURE MONITORING EQUIPMENT, at least a LOW PRIORITY ALARM CONDITION for a category 2 HUMIDIFIER;

to indicate that the MEASURED GAS TEMPERATURE, when averaged over a 5 min period, differs by more than ±2 °C from the SET TEMPERATURE during NORMAL USE.

b) These ALARM CONDITIONS need not be activated during the start-up period or during the transition to a new state of thermal equilibrium following a change in gas flowrate or change in SET TEMPERATURE.

NOTE The requirements for thermal overshoot of 201.12.4.101 apply during these periods of transition.

c) The maximum start-up period in NORMAL USE, the warm-up time for the MEASURED GAS TEMPERATURE to reach the SET TEMPERATURE from a starting temperature of (23 ± 2) °C, shall be disclosed in the instructions for use.

Check compliance by functional testing.

201.12.1.103 * MEASURED GAS TEMPERATURE MONITORING EQUIPMENT

a) The HUMIDIFIER may be equipped with MEASURED GAS TEMPERATURE MONITORING EQUIPMENT that displays the temperature.

b) If equipped, the MEASURED GAS TEMPERATURE MONITORING EQUIPMENT shall

1) have a RATED range of at least 25 °C to 45 °C, and

2) be accurate to ±2 °C over the RATED range.

c) The accuracy of the MEASURED GAS TEMPERATURE MONITORING EQUIPMENT shall be disclosed in the instructions for use.

Check compliance by inspection of the instructions for use, functional testing and with the tests of Annex BB.

201.12.4 Protection against hazardous output

Additional subclause:

201.12.4.101 * Thermal overshoot

In NORMAL USE and SINGLE FAULT CONDITIONS and over the RATED flowrate range and at the maximum RATED operating temperature, the DELIVERED GAS TEMPERATURE of the HUMIDIFIER shall not exceed an energy equivalent to 43 °C and 100 % RELATIVE HUMIDITY (a specific enthalpy not to exceed 197 kJ/m³ dry air) when averaged over 120 s.

Table 201.103 contains examples of combinations of temperature and RELATIVE HUMIDITY for air with such a specific enthalpy.

NOTE HUMIDIFIERS are commonly used with air and oxygen mixtures. The thermal overshoot limit of 197 kJ/m³ of dry gas when averaged over 120 s also applies to other gas mixtures, such as helium-oxygen mixtures, where the instructions for use includes use with other gas mixtures. The temperature limit is likely different for other gas mixtures and will need to be calculated.

Check compliance with the following test.

a) Assemble the HUMIDIFIER, BREATHING TUBES and ACCESSORIES as indicated in the instructions for use.

b) Fill the HUMIDIFICATION CHAMBER to its maximum level prior to each test. Operate the HUMIDIFIER at its minimum RATED flowrate and wait 30 min.

c) Quickly adjust the flowrate to the maximum RATED flowrate and with a sampling period no greater than 2 s, measure the DELIVERED GAS TEMPERATURE for the next 240 s.

Table 201.103 — Examples of permissible combinations of temperature and RELATIVE HUMIDITY in air

Temperature °C	RELATIVE HUMIDITY %
43	100
44	95
45	90
48	76
50	71

d) Calculate the specific enthalpy using the method of Annex DD.

e) Confirm that the specific enthalpy averaged over 120 s does not exceed 197 kJ/m³ during the 240 s measurement period.

f) Repeat b) to e), starting at the maximum RATED flowrate and quickly adjusting to the minimum RATED flowrate.

g) Operate the HUMIDIFIER at its minimum RATED flowrate and maximum RATED SET TEMPERATURE and wait 30 min.

h) Turn off the gas flow for 3 min.

i) Return the gas flow to the minimum RATED flowrate and with a sampling period no greater than 2 s, measure the DELIVERED GAS TEMPERATURE and AIRWAY PRESSURE for the next 240 s.

j) Calculate the specific enthalpy using the method of Annex DD.

k) Confirm that the specific enthalpy averaged over 120 s does not exceed 197 kJ/m³ during the 240 s measurement period.

l) Repeat g) to k), starting at the average RATED flowrate.

m) Repeat g) to k), starting at the maximum RATED flowrate.

n) Operate the HUMIDIFIER with no flow and wait 30 min.

o) Quickly adjust the flowrate to the maximum RATED flowrate and with a sampling period no greater than 2 s, measure the DELIVERED GAS TEMPERATURE and AIRWAY PRESSURE for the next 240 s.

NOTE Equipment modifications can be necessary for a HUMIDIFIER that is activated by its integrated flow generator.

p) Calculate the specific enthalpy using the method of Annex DD.

q) Confirm that the specific enthalpy does not exceed 197 kJ/m³ when averaged over 120 s during the 240 s measurement period.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 13 applies, except as follows.

Additional subclauses:

201.13.1.101 * Additional specific HAZARDOUS SITUATIONS

In NORMAL CONDITION and SINGLE FAULT CONDITION, a HUMIDIFIER shall be so constructed that the following HAZARDOUS SITUATIONS shall not occur:

a) the volume of liquid exiting the HUMIDIFICATION CHAMBER outlet shall not exceed:

1) 1,0 ml in 1 min or 2,0 ml in 1 h when intended for use with PATIENTS weighing less than 5 kg;

2) 5 ml in 1 min or 20 ml in 1 h for all other PATIENTS.

Check compliance with functional testing.

201.13.2.101 Additional specific SINGLE FAULT CONDITIONS

A HUMIDIFIER shall be so constructed that the following SINGLE FAULT CONDITIONS shall not cause an unacceptable RISK:

a) operation of the HUMIDIFIER without any liquid;

b) if the HUMIDIFIER includes a sensor or sensors that are responsible for the condition of the gas delivered to the PATIENT, any failure of a sensor or the sensing system.

EXAMPLE 1 Sensor single open-circuit.

EXAMPLE 2 Sensor single short-circuit.

EXAMPLE 3 Sensor disconnected from the HUMIDIFIER control system.

EXAMPLE 4 Sensor disconnected from BREATHING TUBE or HUMIDIFIER.

Check compliance by functional testing and inspection of RISK MANAGEMENT FILE.

201.13.102 * Independence of HUMIDIFICATION control function and related RISK CONTROL measures

a) A SINGLE FAULT CONDITION shall not cause the HUMIDIFIER-control function and the corresponding PROTECTION DEVICE to fail simultaneously.

b) A SINGLE FAULT CONDITION shall not cause

1) the HUMIDIFIER-control function and the corresponding MONITORING EQUIPMENT, or

2) the HUMIDIFIER-control function and the corresponding ALARM SYSTEM

to fail in such a way that the loss of the HUMIDIFIER-control function is not detected.

Check compliance by inspection and functional testing.

201.14 Programmable electrical medical systems (pems)

IEC 60601-1:2005+AMD1:2012, Clause 14 applies, except as follows.

201.14.1 General

Amendment (extend the last paragraph prior to the compliance check with):

aa) The humidity and temperature control PESS of the HUMIDIFIER PEMS without an independent hardware RISK CONTROL measure shall be considered as

100) for a category 1 HUMIDIFIER, software safety Class C as defined in IEC 62304:2006+AMD1:2015.

101) for a category 2 HUMIDIFIER, at least software safety Class B as defined in IEC 62304:2006+AMD1:2015.

bb) The software safety class for a Category 2 HUMIDIFIER shall not be reduced from Class B to Class A with an independent hardware RISK CONTROL measure.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005+AMD1:2012, Clause 15 applies, except as follows.

Additional subclause:

201.15.101 Mode of operation

A HUMIDIFIER shall be suitable for CONTINUOUS OPERATION.

Check compliance by inspection.

201.16 ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 16 applies, except as follows.

Additional subclause:

201.16.1.101 Additional general requirements for ME SYSTEMS

ACCESSORIES connected to the HUMIDIFIER shall be considered to form an ME SYSTEM with the HUMIDIFIER.

Check compliance by application of the relevant tests of IEC 60601-1:2005+AMD1:2012.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Clause 17 applies.

Additional clauses:

201.101 BREATHING SYSTEM connectors and ports

201.101.1 * General

a) If a HUMIDIFIER is intended to be placed in a BREATHING SYSTEM, any conical connector shall

   1) comply with ISO 5356-1:2015, or

   2) not engage with those connectors or with connectors complying with ISO 80369-1:2010.

b) A non-conical connector shall

   1) not engage with a conical connector complying with ISO 5356-1:2015, unless they comply with the engagement, disengagement and leakage requirements of that standard.

Check compliance by application of the tests of ISO 5356-1:2015 and functional testing.

201.101.2 PATIENT-CONNECTION PORT

If equipped, the PATIENT-CONNECTION PORT shall be one of the following:

a) a female 15 mm conical connector complying with ISO 5356-1:2015;

b) a coaxial 15 mm/22 mm conical connector complying with ISO 5356-1:2015.

Check compliance by application of the tests of ISO 5356-1:2015.

201.101.3 FLOW-DIRECTION-SENSITIVE components

Any OPERATOR-detachable FLOW-DIRECTION-SENSITIVE COMPONENT of the HUMIDIFIER shall be so designed that it cannot be fitted in such a way that it presents an unacceptable RISK to the PATIENT.

Check compliance by inspection of OPERATOR*-detachable* FLOW-DIRECTION-SENSITIVE COMPONENTS *and inspection of the* RISK MANAGEMENT FILE*.*

201.101.4 * ACCESSORY port

If provided, each ACCESSORY port of the HUMIDIFIER, BREATHING SYSTEM, its parts and ACCESSORIES shall

a) comply with ISO 80369-1:2010, and

b) be provided with a means to secure the ACCESSORY in position and a means to secure closure after removal of the ACCESSORY.

NOTE 1 It is expected that the RESP-125 (R1) connector of ISO 80369-2[11] will meet this criterion.

NOTE 2 This port is generally used for measuring pressure, sampling of gases or for introduction of therapeutic aerosols.

Check compliance by inspection and application of the tests of ISO 80369-1:2010.

201.101.5 Monitoring probe port

If a port is provided for introduction of a monitoring probe, it:

a) shall not be compatible with connectors specified in ISO 5356-1:2015;

b) shall be provided with a means to secure the probe in position and a means to secure closure after removal of the probe.

Check compliance by inspection and application of the tests of ISO 5356-1:2015.

201.101.6 Oxygen inlet port

a) An oxygen inlet connector of the HUMIDIFIER, BREATHING SYSTEM, its parts and ACCESSORIES that is OPERATOR-accessible without the use of a TOOL shall comply with ISO 80369-1:2010.

b) A HUMIDIFIER with this inlet connector shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE with oxygen supply systems up to 600 kPa, in NORMAL CONDITION.

NOTE It is expected that the RESP-6000 (R2) connector of ISO 80369-2[11] will meet this criterion.

Check compliance by functional testing and application of the tests of ISO 80369-1:2010.

201.101.7 Other connectors

If the HUMIDIFIER, BREATHING SYSTEM, its parts or ACCESSORIES is fitted with any other type of connector, these connectors:

a) shall mate with BREATHING TUBES that comply with ISO 5367:2014;

b) shall not accept or permit connection with either

1) the 15 mm or 22 mm conical connectors complying with ISO 5356-1:2015, or

2) the connectors complying with ISO 80369-1:2010.

Check compliance by inspection and application of the tests of ISO 5367:2014.

201.101.8 Removable temperature sensors and ports

201.101.8.1 Security

When the sensors or mating ports are engaged in NORMAL USE, the connection shall not become disconnected under the conditions of

a) no flow, or

b) maximum RATED flowrate.

Check compliance by functional testing under the conditions of no flow or maximum RATED flowrate.

201.101.8.2 * Leakage

The leakage from an engaged sensor or mating port shall not exceed 5 ml/min at a pressure of 60 cmH_2O.

Check compliance by functional testing.

201.101.8.3 Construction

Removable sensors and ports shall

a) meet the dimensional requirements of Annex EE, or

b) be sufficiently different that they cannot be interchanged with those that do.

Check compliance by inspection and functional testing or by application of the tests of Annex EE.

201.101.9 Other orifices

If the HUMIDIFIER, BREATHING SYSTEM, its parts and ACCESSORIES incorporate an independent filling or ACCESSORY orifice (e.g. an air entrainment or a heater orifice), that orifice shall not accept any of

a) the connectors specified in ISO 5356-1:2015, or

b) the connectors complying with ISO 80369-1:2010.

Check compliance by inspection.

201.102 Requirements for the BREATHING SYSTEM and ACCESSORIES

201.102.1 * General

All BREATHING SYSTEMS, their parts and ACCESSORIES shall comply with the requirements of this document, whether they are produced by the MANUFACTURER of the HUMIDIFIER or by another entity ("third-party manufacturer" or healthcare provider).

Check compliance by the tests of this document.

201.102.2 Labelling

a) The MODEL OR TYPE REFERENCE of at least one compatible HUMIDIFIER shall be disclosed in the ACCOMPANYING DOCUMENT, or packaging label provided with each BREATHING SYSTEM or ACCESSORY, compliant with 201.102.1.

b) Statements shall be included in the ACCOMPANYING DOCUMENT or packaging label of each BREATHING SYSTEM, part or ACCESSORY to the effect that:

   1) breathing systems, their parts and accessories are validated for use with specific humidifiers;

   2) incompatible parts can result in degraded performance which can affect safety;

   3) the responsible organization is accountable for the compatibility of the humidifier and all of the parts and accessories used to connect to the patient and other equipment before use.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

201.102.3 * BREATHING TUBES

201.102.3.1 Non-heated BREATHING TUBES

BREATHING TUBES, other than heated BREATHING TUBES, intended for use in the BREATHING SYSTEM shall comply with ISO 5367:2014 at the maximum HUMIDIFICATION OUTPUT of the HUMIDIFIER.

Check compliance by application of the tests of ISO 5367:2014 while connected to the specified HUMIDIFIER operated at its maximum RATED output.

201.102.3.2 Heated BREATHING TUBES

Heated BREATHING TUBES intended for use in the BREATHING SYSTEM shall not collapse on bending, occlude or otherwise cause loss of BASIC SAFETY or ESSENTIAL PERFORMANCE when the BREATHING TUBES are subject to the maximum RATED output power of the specified HEATED BREATHING TUBE CONTROLLER, including under conditions of no flow.

Check compliance by application of the tests of ISO 5367:2014, Annex E and Annex G, while connecting the HEATED BREATHING TUBES to the specified HEATED BREATHING TUBE CONTROLLER operated at its maximum RATED output at both the maximum flowrate and no flow conditions.

201.103 LIQUID CONTAINER

201.103.1 Liquid level

For category 1 HUMIDIFIERS, means shall be provided to permit the OPERATOR to determine the liquid level:

a) in the LIQUID CONTAINER;

b) if provided, the LIQUID RESERVOIR;

without dismantling the HUMIDIFIER.

Check compliance by inspection.

201.103.2 Filling cap

Reusable filling caps, if provided, shall be tethered to part of the HUMIDIFIER.

Check compliance by inspection.

201.104 FUNCTIONAL CONNECTION

201.104.1 * General

BASIC SAFETY and ESSENTIAL PERFORMANCE of the HUMIDIFIER shall be maintained if

a) connections to the FUNCTIONAL CONNECTION of a HUMIDIFIER, including the heated BREATHING TUBE controller, are disrupted, or

b) the equipment connected to those parts fails.

Check compliance by functional testing.

201.104.2 * Connection to an electronic health record

A Category 1 HUMIDIFIER should be equipped with a FUNCTIONAL CONNECTION that permits data transmission from the HUMIDIFIER to, for example, an electronic health record.

201.104.3 * Connection to a DISTRIBUTED ALARM SYSTEM

A Category 1 HUMIDIFIER should be equipped with a FUNCTIONAL CONNECTION that permits connection to a DISTRIBUTED ALARM SYSTEM.

201.104.4 Connection for remote control

A HUMIDIFIER may be equipped with a FUNCTIONAL CONNECTION for external control of the HUMIDIFIER.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014 applies except as follows.

Addition:

202.4.3.1 Configurations

IEC 60601-1-2:2014 applies except as follows.

Amendment (add after the last dash of 4.3.1):

aa) attachment of the breathing tubes to the humidifier or heated breathing tube controller;

bb) if applicable, attachment of ACCESSORIES as necessary to achieve the BASIC SAFETY and ESSENTIAL PERFORMANCE of the HUMIDIFIER.

202.5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

Amendment [add note to list element b)]:

NOTE The requirements of this document are not considered deviations or allowances.

Addition:

202.8.1.101 * Additional general requirements

a) The following degradations, if affecting BASIC SAFETY, shall not be allowed:

1) component failures;

2) changes in programmable parameters or settings;

3) reset to default settings;

4) change of operating mode;

5) the specific enthalpy at the HUMIDIFIER output averaged over 120 s exceeding 197 kJ/m³.

NOTE 1 Table AA.1 indicates the conversion from the values of dew point to the units of mg/l (reference BTPS) for use when using a dew point hygrometer to monitor the HUMIDIFICATION OUTPUT when determining the specific enthalpy at the HUMIDIFIER output.

NOTE 2 MANUFACTURERS are encouraged to consider monitoring a control signal to the heater to determine if controlled heating is occurring in lieu of monitoring specific enthalpy.

b) The HUMIDIFIER may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use during IMMUNITY testing) that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.

206 Usability

IEC 60601-1-6:2010+AMD1:2013 applies except as follows.

For a HUMIDIFIER, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) observing monitored humidification parameters;

b) filling the LIQUID CONTAINER and, if provided, the LIQUID RESERVOIR;

c) observing the water level in the LIQUID CONTAINER and, if provided, in the LIQUID RESERVOIR;

d) configuring the ACCESSORIES including connection of the detachable parts to the HUMIDIFIER;

EXAMPLE 1 Heated breathing tube controller, water trap, breathing tubes, breathing system filter, monitoring equipment.

e) connecting the PATIENT-CONNECTION PORT to the PATIENT-interface;

f) disconnecting the PATIENT-CONNECTION PORT from the PATIENT-interface;

g) reprocessing the ACCESSORIES;

h) starting the HUMIDIFIER from power off;

i) turning off the HUMIDIFIER;

j) performing a basic pre-use functional check of the HUMIDIFIER including the ALARM SIGNALS.

The following functions, if available, shall also be considered PRIMARY OPERATING FUNCTIONS:

k) connecting the HUMIDIFER to the flow source (e.g. ventilator);

l) disconnecting the HUMIDIFER from the flow source (e.g. ventilator);

m) setting the OPERATOR-adjustable controls, including:

1) switching between different humidification modes;

2) setting humidification control parameters;

3) setting ALARM LIMITS;

4) inactivating ALARM SIGNALS;

n) starting humidification from standby;

o) activating standby.

The following actions associated with humidification also shall be considered PRIMARY OPERATING FUNCTIONS:

NOTE For the purposes of this document, the following functions are considered PRIMARY OPERATING FUNCTIONS even though they are not performed on the HUMIDIFIER'S OPERATOR-EQUIPMENT INTERFACE.

p) adding medication to the gas flowing into the PATIENT;

EXAMPLE 2 Injecting fluids into the ancillary port connection of the BREATHING SYSTEM.

q) for a TRANSIT-OPERABLE equipment, positioning the PATIENT and the equipment on a wheelchair or trolley.

206.5 Replacement of requirements given in IEC 62366[17]

Amendment (add at the end of the last paragraph of Clause 5):

The summary of the application specification shall include HUMIDIFIER classification as specified in 201.6.101.

NOTE The "application specification" of IEC 62366[17] is called the USE SPECIFICATION in IEC 62366–1:2015[18].

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006+AMD1:2012 applies except as follows.

Additional subclauses:

208.6.8.4.101 * Additional requirements for termination of ALARM SIGNAL inactivation

For category 1 HUMIDIFIERS, the duration of AUDIO PAUSED or ALARM PAUSED for the ALARM CONDITIONS required by this document shall not exceed 120 s without OPERATOR intervention.

NOTE This permits an OPERATOR to deliberately extend the duration of AUDIO PAUSED by direct action.

Check compliance by functional testing.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015 applies except as follows.

211.10.1.1 General requirements for mechanical strength

Amendment (add the before first paragraph):

a) The tests of IEC 60601-1-11:2015, Clause 10 and of IEC 60601-1:2005+AMD1:2012, 15.3 shall be performed on the same sample of the HUMIDIFIER after the cleaning and disinfection PROCEDURES of 201.11.6.6 of this document have been performed unless there are no cleaning and disinfection PROCEDURES specified in the instructions for use.

b) If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE shall be so tested.

c) A separate sample of the HUMIDIFIER may be used for each specified PROCEDURE.

IEC 60601-1:2005+AMD1:2012, annexes apply, except as follows.

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+AMD1:2012, Annex C of the general standard applies, except as follows.

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

201.C.1.101 Marking on the outside of a HUMIDIFIER or its parts

Additional requirements for marking on the outside of a HUMIDIFIER or its parts are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of a HUMIDIFIER or its parts

Description of marking	Subclause
Any particular storage and/or handling instructions, if applicable	201.7.2.101 b)
Any particular warnings and/or precautions relevant to the immediate operation of the HUMIDIFIER, if applicable	201.7.2.101 c)
Arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS, if applicable	201.7.2.101 d)
Containing natural rubber latex, if applicable	201.7.2.13.101
For ACCESSORIES supplied separately, indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the HUMIDIFIER, if applicable	201.7.2.4.101
For ACCESSORIES supplied separately, the requirements of 201.7.2.101, 201.7.2.13.101 and 201.7.2.17.101	201.7.2.4.101
For each HUMIDIFIER, part and ACCESSORY, contains phthalates, if applicable	201.11.7
For packaging, containing natural rubber latex, if applicable	201.7.2.17.101 c)
For packaging, description of the contents	201.7.2.17.101 a)
For packaging, identification reference to the batch, type or serial number	201.7.2.17.101 b)
Maximum and minimum liquid levels	201.7.2.101 a)
Pressure at which the pressure-relief PROTECTION DEVICE opens, if provided	201.7.2.101 e)

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition:

201.C.4.101 ACCOMPANYING DOCUMENTS, general, of a HUMIDIFIER

Additional requirements for ACCOMPANYING DOCUMENTS, general, of a HUMIDIFIER are found in Table 201.C.102.

Table 201.C.102 — ACCOMPANYING DOCUMENTS, general, of a HUMIDIFIER

Description of requirement	Subclause
For each BREATHING SYSTEM and ACCESSORY, the MODEL OR TYPE REFERENCE of at least one compatible HUMIDIFIER	201.102.2
For each BREATHING SYSTEM, part and ACCESSORY, a statement to the effect that breathing systems, their parts and accessories are validated for use with specific humidifiers	201.102.2 a)
For each BREATHING SYSTEM, part and ACCESSORY, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b)
For each BREATHING SYSTEM, part and ACCESSORY, a statement to the effect that the responsible organization is accountable for the compatibility of the humidifier and all of the parts and accessories used to connect to the patient before use	201.102.2 c)
HUMIDIFIER is a high flow device warning, if applicable	201.4.11.101.2 3) iii)
Maximum time-weighted average input flowrate for each gas, if applicable	201.4.11.101.2 3) i)
Maximum transient input flowrate for each gas, if applicable	201.4.11.101.2 3) ii)
Name or trade name and address of the MANUFACTURER and where the MANUFACTURER does not have an address within the locale an authorized representative	201.7.9.1
Units of measure for volumes, flows and leakages expressed as STPD or BTPS, as appropriate	201.7.4.3

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use

Addition:

201.C.5.101 ACCOMPANYING DOCUMENTS, instructions for use of a HUMIDIFIER

Additional requirements for ACCOMPANYING DOCUMENTS, instructions for use of a HUMIDIFIER are found in Table 201.C.103.

Table 201.C.103 — ACCOMPANYING DOCUMENTS, instructions for use of a HUMIDIFIER

Description of requirement	Subclause
Accuracy of the MEASURED GAS TEMPERATURE MONITORING EQUIPMENT	201.12.1.103
Any adverse effect of any recommended ACCESSORY on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the HUMIDIFIER, if applicable	201.7.9.2.14.101 c)
Any natural rubber latex-containing components, if applicable	201.7.2.13.101
Description of the INTERNAL ELECTRICAL POWER SOURCE care and maintenance PROCEDURES, including instructions for recharging or replacement, if applicable	201.7.9.2.13 b)
Description of the periodic visual safety inspections that should be performed by the OPERATOR	201.7.9.2.13 a)
Disclosed application specification includes the HUMIDIFIER classification as specified in 201.6.101	206.5
Disclosure of any restrictions on the placing of components within the BREATHING SYSTEM, if applicable	201.7.9.2.14.101 b)
For a HUMIDIFIER, its parts or ACCESSORIES intended for single-use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the HUMIDIFIER, its parts or ACCESSORIES would be reused	201.7.9.2.1.102 a)
For a HUMIDIFIER, its parts or ACCESSORIES intended for single-use, that it is single use and the intended duration of use	201.7.9.2.1.102 b)
For ACCESSORIES supplied separately where marking the ACCESSORY is not practicable, the requirements of 201.7.2.4.101, 201.7.2.13.101 and 201.7.2.17.101, if not marked	201.7.2.4.101
For each HUMIDIFIER, part and ACCESSORY, information on RESIDUAL RISKS for children or treatment of pregnant or nursing women and, if applicable, on appropriate precautionary measures for devices that contain phthalates	201.11.7
For the LAY OPERATOR instructions, an explanation of the meaning of the IP classification	201.7.9.2.9.101.1 b)
For the LAY OPERATOR instructions, an indication of the expected duration of operation between refills	201.7.9.2.9.101.1 d)
For the LAY OPERATOR instructions, conditions under which the HUMIDIFIER maintains the accuracy of controlled and displayed variables	201.7.9.2.9.101.1 a)
For the LAY OPERATOR instructions, method by which all of the ALARM SIGNALS can be functionally tested to determine if they are operating correctly, if equipped with an ALARM SYSTEM	201.7.9.2.8.101
For the LAY OPERATOR instructions, the maximum volume of water, expressed in ml, available for vaporization contained in the LIQUID CONTAINER and, if provided, in the LIQUID RESERVOIR	201.7.9.2.9.101.1 c)
For the LAY OPERATOR instructions, the specifications of any ACCESSORIES or equipment required to perform the tests described in 201.7.9.2.8.101	201.7.9.2.8.101

Table 201.C.103 *(continued)*

Description of requirement	Subclause
For the supervising clinician or the healthcare professional OPERATOR instructions and for a HUMIDIFIER that entrains air for the purpose of diluting oxygen, a recommendation that the oxygen concentration be measured at the point of delivery to the PATIENT	201.7.9.2.9.101.2 k)
For the supervising clinician or the healthcare professional OPERATOR instructions and for a HUMIDIFIER that entrains air for the purpose of diluting oxygen, a statement to the effect that the oxygen concentration can be affected by a partial obstruction downstream of the HUMIDIFIER	201.7.9.2.9.101.2 k)
For the supervising clinician or the healthcare professional OPERATOR instructions, the essential technical characteristics of each recommended BREATHING SYSTEM FILTER, if applicable	201.7.9.2.9.101.2 j)
For the supervising clinician or the healthcare professional OPERATOR instructions, the gas leakage of the HUMIDIFIER or individual components, as appropriate, at the maximum RATED pressure	201.7.9.2.9.101.2 f)
For the supervising clinician or the healthcare professional OPERATOR instructions for use, the information contained in instructions for use for LAY OPERATOR	201.7.9.2.1.101
For the supervising clinician or the healthcare professional OPERATOR instructions, the known adverse effects on the performance of the HUMIDIFIER when exposed to, for example, electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transient magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference	201.7.9.2.9.101.2 i)
For the supervising clinician or the healthcare professional OPERATOR instructions, the location in the HUMIDIFIER or ACCESSORIES to which the displayed MEASURED GAS TEMPERATURE is referenced	201.7.9.2.9.101.2 e)
For the supervising clinician or the healthcare professional OPERATOR instructions, the maximum DELIVERED GAS TEMPERATURE, if the HUMIDIFIER is not provided with a means of continuously indicating the MEASURED GAS TEMPERATURE	201.7.9.2.9.101.2 d)
For the supervising clinician or the healthcare professional OPERATOR instructions, the MAXIMUM LIMITED PRESSURE of the HUMIDIFIER and ACCESSORIES	201.7.9.2.9.101.2 a)
For the supervising clinician or the healthcare professional OPERATOR instructions, the MAXIMUM OPERATING PRESSURE	201.7.9.2.9.101.2 b)
For the supervising clinician or the healthcare professional OPERATOR instructions, the RATED range of environmental operating conditions (temperature and altitude) of NORMAL USE	201.7.9.2.9.101.2 c)
For the supervising clinician or the healthcare professional OPERATOR instructions, the minimum, maximum and RATED range of flowrate, GAS PATHWAY resistance and GAS PATHWAY compliance of the assembled OPERATOR-detachable parts, over which the accuracies of set and monitored humidification are maintained, unless the HUMIDIFIER is integrated into other equipment	201.7.9.2.9.101.2 g)
For the supervising clinician or the healthcare professional OPERATOR instructions, pressure drop, as a function of flowrate, across the HUMIDIFIER and ACCESSORIES or individual components, unless the HUMIDIFIER is integrated into other equipment	201.7.9.2.9.101.2 h)
HUMIDIFICATION OUTPUT (in mg/l) over the RATED range of gas flowrates and settings	201.12.1.101

Table 201.C.103 *(continued)*

Description of requirement	Subclause
List of the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT, parts or ACCESSORIES can tolerate	201.7.9.2.12
Maximum start-up period in NORMAL USE	201.12.1.102
Processing or reprocessing PROCESS instructions for the HUMIDIFIER and its ACCESSORIES	201.11.6.6
Quality and purity of the water to be used in the HUMIDIFIER, and that adding other substances can have adverse effects	201.7.9.2.1.102 c)
Recommended mounting methods and other relevant installation information	201.7.9.2.6
Separate instructions for use for LAY OPERATOR	201.7.9.2.1.101
Separate instructions for use for supervising clinician or the healthcare professional OPERATOR	201.7.9.2.1.101
Set of ACCESSORIES and, if applicable, the ME EQUIPMENT necessary for the HUMIDIFIER'S INTENDED USE	201.7.9.2.14.101 a)
Warning statement to the effect that covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient, if applicable	201.7.9.2.2.101 d)
Warning statement to the effect that do not add any attachments or accessories to the humidifier that are not listed in the instruction for use of the humidifier or accessory or the humidifier might not function correctly affecting the quality of the therapy or injuring the patient	201.7.9.2.2.101 a)
Warning statement to the effect that do not use the humidifier at an altitude above [insert maximum RATED altitude] or outside a temperature of [insert RATED temperature range]. Using the humidifier outside of this temperature range or above this altitude can affect the humidifier performance which consequently can result in patient death	201.7.9.2.2.101 b)
Warning statement to the effect that to prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used	201.7.9.2.2.101 c)
Which portions of the GAS PATHWAYS through the HUMIDIFIER can become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION	201.7.9.2.12

201.C.6 ACCOMPANYING DOCUMENTS, technical description

Addition:

201.C.6.101 ACCOMPANYING DOCUMENTS, technical description of a HUMIDIFIER

Additional requirements for ACCOMPANYING DOCUMENTS, technical description of a HUMIDIFIER are found in Table 201.C.104.

Table 201.C.104 — ACCOMPANYING DOCUMENTS, technical description of a HUMIDIFIER

Description of requirement	Subclause
Description of a method for checking the function of ALARM SYSTEM for each of the ALARM CONDITIONS of this document, if not performed automatically at start-up	201.7.9.3.101
Disclosure of the interdependence of control functions	201.7.9.3.1.101 a)
Disclosure of the measurement uncertainty for each disclosed tolerance	201.5.101.3
Listing of which ALARM CONDITIONS that are checked automatically at start-up	201.7.9.3.101
Statement to the effect that the responsible organization should ensure the compatibility of the humidifier and all of the parts and accessories intended to be used to connect to the patient prior to use	201.7.9.3.1.101 b)

Annex D
(informative)

Symbols on Marking

IEC 60601-1:2005+AMD1:2012, Annex D applies, except as follows.

Addition:

Table 201.D.2.101 — Additional symbols on marking

No	Symbol	Reference	Title and description
1	LOT	IEC 80878:2015[16] ISO 7000-2492[3] Symbol 5.1.5 ISO 15223-1:2016	Batch code To identify the MANUFACTURER's batch or lot code, for example, on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.
2	REF	IEC 80878:2015[16] ISO 7000-2493[3] Symbol 5.1.6 ISO 15223-1:2016	Catalogue number To identify the MANUFACTURER's catalogue number, for example, on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
3	SN	IEC 80878:2015[16] ISO 7000-2498[3] Symbol 5.1.7 ISO 15223-1:2016	Serial number To identify the MANUFACTURER's serial number, for example, on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.
4	LATEX	IEC 80878:2015[16] ISO 7000-2725[3] Symbol 5.4.5 ISO 15223-1:2016	Contains or presence of (natural rubber latex) On medical devices: to indicate that the equipment contains the identified product or substance. NOTE Replace "XXX" with the symbol or other identification of the substance that is contained or present, where LATEX is used for natural rubber latex.
5	XXX	IEC 80878:2015[16] ISO 7000-2725[3] EN 15986:2011	Contains or presence of [XXX] On medical devices: to indicate that the equipment contains the identified product or substance. NOTE Replace "XXX" with the symbol or other identification of the substance that is contained or present, where PHT is used for phthalate.

Additional Annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides rationale for the important requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this document, with clause and subclause numbers parallel to those in the body of the document.

The clauses and subclauses in this annex have been so numbered to correspond to the clauses and subclauses in this document to which they refer. The numbering is, therefore, not consecutive.

Subclause 201.1.1 — Scope

An ACTIVE HME is also electrically powered ME EQUIPMENT that contains heater elements to vaporize liquid water that is added into the breathing gas. This water vapour augments that delivered to the respiratory tract of the PATIENT from the HME. Most requirements of this document therefore apply. Those requirements that do not apply are clearly indicated.

Some HUMIDIFIERS have built-in flow sources that generate the flow of breathing gas, for example, sleep apnoea therapy equipment. For such ME EQUIPMENT, most requirements of this document apply. Those requirements that do not apply, such as pressure drop, are clearly indicated.

Subclause 201.4.3.101 — Additional requirements for ESSENTIAL PERFORMANCE

The ESSENTIAL PERFORMANCE of a HUMIDIFIER fundamentally is maintaining its HUMIDIFICATION OUTPUT or informing the OPERATOR that this performance is not being attained. However, accurate and timely measurements of HUMIDIFICATION OUTPUT are problematic at best.

Given the nature of the physics of humidification, short transient changes in HUMIDIFICATION OUTPUT are not clinically significant. Therefore, changes in and not the absolute HUMIDIFICATION OUTPUT averaged over time are used as acceptance criteria following the specific tests required by this document to demonstrate the maintenance of ESSENTIAL PERFORMANCE.

The MANUFACTURER should consider the timeliness of the notification of the OPERATOR provided by the ALARM CONDITIONS or indication of abnormal operation when HUMIDIFICATION OUTPUT is not maintained.

Subclause 201.4.6 — ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Since much of the BREATHING SYSTEM is likely to be draped over or around the PATIENT, it is likely to come into direct contact with the PATIENT during NORMAL USE. Additionally, the GAS PATHWAYS conduct fluids into or out of the PATIENT. As such, the GAS PATHWAYS of the BREATHING SYSTEM and

the HUMIDIFIER need to be investigated regarding biocompatibility and compatibility with substances that might pass into the PATIENT via the GAS PATHWAYS. Also of concern are electrical HAZARDS should any circuitry be incorporated into the BREATHING SYSTEM (particularly for heated BREATHING SYSTEMS). By ensuring that those items are subject to the requirements for APPLIED PARTS, these issues are addressed by the requirements already in the general standard.

Subclause 201.11.101 — Additional requirements for pressurized gas input

A HUMIDIFIER designed to be connected to a pressurized gas supply is required to continue to operate reliably throughout its RATED range of supply pressures, and these pressures can only be maintained if the HUMIDIFIER in NORMAL CONDITION does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that these HUMIDIFIERS should be designed to prevent an unacceptable RISK under possible SINGLE FAULT CONDITIONS of the pressurized gas supply.

Pressurized medical gas supplies, including MEDICAL GAS PIPELINE SYSTEMS and cylinder pressure regulators conforming to current relevant standards, supply gas-specific terminal outlets at a pressure that is within an internationally agreed pressure range of 280 kPa to 600 kPa under NORMAL CONDITION. It is expected that HUMIDIFIERS should operate to their declared specification at any supply pressure within this range.

In the case of a pressure regulator failure, the gas supply pressure could rise to the pressure regulator's supply pressure, which can be cylinder (tank) pressure. To safeguard against this or similar eventualities, gas-specific medical gas supply systems are required to be provided with a means to limit their output pressure to not more than 1 000 kPa. All gas-powered ME EQUIPMENT should be designed so as not to present an unacceptable RISK if its supply pressure rises up to this value.

HUMIDIFIERS with maximum RATED input pressures exceeding 600 kPa are required to fulfil these conditions at up to twice their maximum RATED input pressure.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, MEDICAL GAS PIPELINE SYSTEMS supplying compressed medical gases through gas-specific terminal outlets are designed so that they can maintain this pressure at the input of gas-powered devices while supplying steady-state flowrates up to 60 l/min at a single outlet connected directly to the pipeline. Account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop, at 60 l/min, across the terminal unit and the hose assembly connecting the device to the pipeline.

The MEDICAL GAS PIPELINE SYSTEM is also required to be capable of supplying sufficient gas that this flow can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the MEDICAL GAS PIPELINE SYSTEM by the application of a "diversity factor", a factor agreed between the supplier and RESPONSIBLE ORGANIZATION to be appropriate for each section of the installation according to the designated purpose of each area supplied. Recommended diversity factors are formulated to ensure that the MEDICAL GAS PIPELINE SYSTEM is capable of supplying an average flowrate of 60 l/min to the required proportion of terminal outlets. However, if the flowrate demand from many adjacent ME EQUIPMENT exceeds 60 l/min, there is an increased possibility that the HUMIDIFIER input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the terminal unit and input hose assembly (also because of the flow-drop characteristic in the case of pressure regulators supplying a single terminal outlet).

In addition to steady-state flowrates of 60 l/min, the switching of the internal pneumatic system and the operation of a PATIENT demand system can result in ME EQUIPMENT requiring transient

input flowrates far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimize the pressure drop, such transient demands can generally be accommodated from the gas within the pipes of the MEDICAL GAS PIPELINE SYSTEM. There can be temporary pressure drops of the input pressure at the inlet of the ME EQUIPMENT, to below 280 kPa, due to transient flowrates in excess of 200 l/min (over 3 s) but most of these drops will be within the supply hose assemblies specified by the MANUFACTURER. MANUFACTURERS need to evaluate their own designs to establish whether any consequent transient pressure drop affects the performance of their ME EQUIPMENT when used with recommended supply hose configurations and when connected to alternative gas-specific terminal outlets, such as those fitted to cylinder pressure regulators conforming to ISO 10524-1.

ME EQUIPMENT that can draw greater average or transient flows during INTENDED USE are permitted, but their ACCOMPANYING DOCUMENTS are required to disclose those flowrates and warn of the need for a different diversity factor.

The average flowrate of 60 l/min is greater than the test flowrate used during the commissioning of MEDICAL GAS PIPELINE SYSTEMS. In itself, this should be of no concern because the specific conditions specified for the test do not allow a direct comparison between the two values. The committee responsible for pipeline standards, ISO/TC 121/SC 6, in consultation with ISO/TC 121/SC 1 and ISO/TC 121/SC 3, agreed to the 60 l/min average flowrate value, and also the 200 l/min for up to 3 s transient flowrates, during the preparation of the current standard for MEDICAL GAS PIPELINE SYSTEMS and were aware of the need to satisfy that specification when finalizing the MEDICAL GAS PIPELINE SYSTEM test requirements.

MANUFACTURERS should be aware that other medical gas supply system standards permit the fitting of gas-specific terminal outlets to supply systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal outlets.

Subclause 201.5.101.2 — Gas flowrate and leakage specifications

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally, one atmosphere (101,325 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,1 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (~37 °C) irrespective of the temperature of the gas delivered to the PATIENT. The volume of a given amount of dry gas increases by about 13,6 % from 0 °C to 37 °C or by 5,8 % from 20 °C to 37 °C.

Gas delivery systems supplying pressurized gas to medical equipment, including HUMIDIFIERS, follow engineering conventions and specify gas quantities and flowrates at STPD conditions. This practice is followed in this document for all requirements concerning gas input.

However, HUMIDIFIERS complying with this document are likely to be used with ventilators that inflate the PATIENT'S lungs relative to a local atmospheric pressure between 70 kPa and 110 kPa. In addition, the gas in the lungs is always saturated with water vapour regardless of the humidity of the gas delivered to the PATIENT'S airway. With a standard temperature of 0 °C, 1 l of gas referenced to STPD (STANDARD TEMPERATURE PRESSURE DRY) can expand the lungs by 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different HUMIDIFIERS, it is essential that the information for all HUMIDIFIERS is referenced to the same standard conditions. Because it is the volume of gas and not the number of molecules that expands the lungs, BTPS is the appropriate set of reference conditions to use.

Subclause 201.5.101.3 — HUMIDIFIER testing errors

When testing HUMIDIFIER performance, several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flows.

Because of the relative significance of these uncertainties, it is important that MANUFACTURERS allow for them when declaring parameter accuracy.

Similarly, it is important for third-party testers to recognize the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a MANUFACTURER determines that a parameter has a tolerance of ±7 % but that the measurement uncertainty is ±3 %, then a parameter tolerance of ±10 % is declared. If a third-party tester subsequently obtains an error of the measured value for that parameter of ±15 %, with a measurement uncertainty of ±5 %, then the third-party tester has to accept the MANUFACTURER'S claim.

Furthermore, the MANUFACTURER is required to disclose the measurement uncertainty for each declared value in order to provide both information to the RESPONSIBLE ORGANIZATION and guidance for a third-party tester as to the needed measurement accuracy when testing to this document.

Subclause 201.7.2.8.2 — Other power sources

The HEATED BREATHING TUBE CONTROLLER MANUFACTURER needs to mark the maximum amount of power that could be delivered to the BREATHING TUBE. This is necessary to permit MANUFACTURERS of BREATHING TUBES to be able to test completely their BREATHING TUBES in order to meet the requirements of 201.102. Since many of the BREATHING TUBE MANUFACTURERS “reverse-engineer” the BREATHING TUBE, the worst-case, maximum power output of the HEATED BREATHING TUBE CONTROLLER needs to be known.

Subclause 201.7.4.3 — Units of measurement

Additional information is found in rationale for 201.5.101.2.

Subclause 201.7.9.2.2.101 — Additional requirements for warnings and safety notices

a)

The OPERATOR should be aware that only the parts or ACCESSORIES listed in the instruction for use have been VALIDATED by the MANUFACTURER. The use of non-VALIDATED parts can represent an unacceptable RISK.

For example,

— a power supply unit other than the one recommended by the MANUFACTURER can be designed and manufactured with inferior quality (poor reliability), can affect the electromagnetic compatibility of the HUMIDIFIER, etc.;

— the connection of parts to the BREATHING SYSTEM that are not listed in the instruction for use can increase the inspiratory or expiratory pathway resistance of the BREATHING SYSTEM or can increase the unintentional leakage of the BREATHING SYSTEM to a level that affects the BASIC SAFETY and ESSENTIAL PERFORMANCE.

Subclause 201.7.9.2.8.101 — Additional requirements for start-up PROCEDURE

In some designs, adequate checking of the ALARM SYSTEM can be performed with a combination of OPERATOR action and the power-on self-test routines that VERIFY the integrity of the software and the integrity of the computer controlling the HUMIDIFIER, as well as the measuring sensors and the ALARM SIGNAL generation.

Subclause 201.7.9.2.9.101.2 — Supervising clinician operating instructions

e)

HUMIDIFIERS can incorporate temperature sensors that measure and display the temperature of the gas at various locations. Many different design approaches exist. The temperature of the gas at the PATIENT-CONNECTION PORT is not always the most clinically useful temperature to display, for example.

EXAMPLE 1 HUMIDIFIER with a heated wire BREATHING TUBE.

Water is heated in a HUMIDIFICATION CHAMBER until the MEASURED GAS TEMPERATURE in the HUMIDIFICATION CHAMBER reaches 37 °C. The gas is then heated in the BREATHING TUBE to 40 °C at the PATIENT-CONNECTION PORT to prevent condensation. The RELATIVE HUMIDITY exiting the HUMIDIFICATION CHAMBER is approximately 100 % and approximately 85 % at the PATIENT-CONNECTION PORT. In addition, because the total heat content (or energy content) of the gas is primarily due to the water vapour content, the total heat content of the gas at the PATIENT-CONNECTION PORT is only slightly higher (due to the increased temperature) than that of the gas exiting the HUMIDIFICATION CHAMBER. This means that once the gas leaves the PATIENT-CONNECTION PORT, rapid cooling will occur until the gas returns to 100 % RELATIVE HUMIDITY and therefore has cooled back to the HUMIDIFICATION CHAMBER temperature (the saturated gas temperature). Following this rapid cooling, the gas will more slowly equilibrate to the temperature of the PATIENT.

In example 1, the MEASURED GAS TEMPERATURE in the HUMIDIFICATION CHAMBER is the best indication of the humidity being delivered to the PATIENT because it represents the saturated gas temperature. The MEASURED GAS TEMPERATURE at the PATIENT-CONNECTION PORT represents a gas temperature that has a RELATIVE HUMIDITY of less than 100 % and is therefore not a good indication of the humidity the PATIENT receives.

EXAMPLE 2 HUMIDIFIER with non-heated BREATHING TUBE.

Water is heated in a HUMIDIFICATION CHAMBER and the resultant vapour is carried by gas flowing through the HUMIDIFIER to an unheated BREATHING TUBE. As the gas travels through the BREATHING TUBE it cools until it reaches 37 °C at the PATIENT-CONNECTION PORT. The RELATIVE HUMIDITY at the PATIENT-CONNECTION PORT is approximately 100 %. To achieve this temperature and humidity, the MEASURED GAS TEMPERATURE in the HUMIDIFICATION CHAMBER can be as high as 55 °C but need only have 42 % RELATIVE HUMIDITY.

In example 2, the MEASURED GAS TEMPERATURE at the PATIENT-CONNECTION PORT is the appropriate indication of the humidity being delivered to the PATIENT.

Therefore, in order to encompass different technologies, it is not appropriate for this document to require a temperature display to show only the temperature delivered at the PATIENT-CONNECTION PORT or at any specific point in the HUMIDIFIER and ACCESSORIES. The MANUFACTURER is required to state clearly in the instructions for use the site to which the displayed MEASURED GAS TEMPERATURE is referenced.

In both examples, BASIC SAFETY and ESSENTIAL PERFORMANCE is maintained as both HUMIDIFIERS meet the requirements of this document (e.g. 201.12.1.101, HUMIDIFICATION OUTPUT at the PATIENT-CONNECTION PORT, and 201.12.4, protection against hazardous output) despite the fact that they are displaying temperatures from different locations.

g)

Resistance to flow anywhere in the GAS PATHWAY can increase the work of breathing. It can also interfere with the effectiveness of intermittent mandatory ventilation (IMV) or triggering mechanisms in lung ventilators.

h)

The internal compliance of the BREATHING SYSTEM, which includes the HUMIDIFIER, needs to be known in order to accurately determine the tidal volume settings of volume-controlled ventilators.

k)

The amount of air entrained by a HUMIDIFIER (e.g. by a Venturi mechanism) is a function of gas velocity. Changes in gas velocity (e.g. because of a partial obstruction of the ventilation circuit) directly affects the oxygen concentration.

Subclause 201.9.4.3.101 — Additional requirements for instability from unwanted lateral movement

TRANSIT-OPERABLE ME EQUIPMENT needs to be capable of being attached to wheelchairs and particularly automobiles when the PATIENT is using the ME EQUIPMENT while travelling. A sudden stop in an automobile can cause ME EQUIPMENT to become a hazardous flying object. This means of attachment should not involve the use of a TOOL as the ME EQUIPMENT needs to be easily attached and detached.

Subclause 201.11.1.2.2 — APPLIED PARTS not intended to supply heat to a PATIENT

The objective of this requirement is to protect the PATIENT from skin burns due to contact with the external surface of the BREATHING TUBE. See rationale to 201.12.4.101 for selecting 44 °C.

Subclause 201.11.6.2 — Overflow in ME EQUIPMENT

HUMIDIFIERS are often mounted on poles in NORMAL USE. However, these HUMIDIFIERS are often not mounted exactly horizontally. The committee felt that a 20° tilt (beyond that of NORMAL USE) could be construed as reasonably foreseeable, and therefore required that the HUMIDIFIER should operate normally, which includes not spilling any liquid, beyond that specified in 201.13.1.101 when operated under NORMAL CONDITIONS at this position. Permanently mounted ME EQUIPMENT is unlikely to be subject to such tilting, nor would ME EQUIPMENT that was intended to be operated while placed on a table or floor, such as sleep apnoea therapy equipment, and so 10° was regarded as a sufficient test angle for these. A 15 % overfill is also reasonably foreseeable and the HUMIDIFIER should operate normally, which includes not spilling any liquid, beyond that specified in 201.13.1.101 when operated under NORMAL CONDITIONS with this amount of overfill.

An ACTIVE HME that is located proximal to the PATIENT can be in any orientation. The least favourable orientation needs to be determined for the overflow test.

Subclause 201.11.6.6 — Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM

The essential principles of ISO 16142-1[7] require that medical devices are not to be operated or used if their condition could compromise the health and safety of the PATIENT on whom they are being used or the employees or third parties interacting with them.

This means that HUMIDIFIERS, their ACCESSORIES and parts cannot be used if there is a potential RISK of the PATIENT, OPERATOR or other person being infected as a result of contact with the HUMIDIFIER, ACCESSORY or part.

Therefore, non-single use HUMIDIFIERS, their ACCESSORIES and parts require an appropriate level of disinfection, depending on their use, but rarely need to be sterile.

Recommendations for hygienic reprocessing of HUMIDIFIERS, their ACCESSORIES and parts are based on the general hygiene requirements for the reprocessing of medical devices and need to take into consideration the special requirements and needs of PATIENT care in the clinical environment[7]. The requirements for hygienic reprocessing of this document are intended to

— make the RESPONSIBLE ORGANIZATION for reprocessing the HUMIDIFIER aware of how to implement these tasks in a responsible manner through appropriate delegation, and

— help all parties involved in the reprocessing of HUMIDIFIERS, their ACCESSORIES and parts to comply with the MANUFACTURER'S instructions.

The cleaning and disinfection PROCEDURES of the MANUFACTURER are also intended to provide practical support to all those involved in PATIENT care in the clinical environment with regard to implementing the hygiene measures required for the PATIENT'S safety.

It should be noted that HUMIDIFIERS, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any HUMIDIFIER that has already been used on another PATIENT is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and reprocessing PROCEDURES are essential to protect the next person handling the device or the next PATIENT on whom the device is used. Hence HUMIDIFIERS, their re-usable ACCESSORIES and parts that have been used are required to undergo a reprocessing PROCESS, following the MANUFACTURER'S instructions, prior to reuse by another PATIENT.

The following basic considerations need to be addressed by the MANUFACTURER when specifying the reprocessing instructions of a HUMIDIFIER, its ACCESSORIES or parts:

a) protecting the PATIENT, the OPERATOR and the RESPONSIBLE ORGANIZATION (including personnel involved in performing the reprocessing PROCESS);

b) the limits of the PROCEDURES used for reprocessing (such as the number of reprocessing cycles);

c) the necessity to guarantee the proven standardized PROCEDURES in a consistently high and verifiable quality, based on an established quality management system.

The recommended reprocessing PROCESS should be determined by:

— the potential degree and type of contamination of the HUMIDIFIER, ACCESSORIES or parts;

— the RISK of infecting another PATIENT resulting from their reuse and the type of application of the HUMIDIFIER.

Special consideration of the possible RISK associated with the contamination of gas-conducting components due to the PATIENT'S re-breathing under SINGLE FAULT CONDITION should be considered.

On the basis of the above, a VERIFIED and VALIDATED documented reprocessing PROCEDURE needs to be specified in such detail so that the outcome is reproducible. An acceptable RESIDUAL RISK from the HAZARD of infection for the next PATIENT can be assumed if:

a) the documented reprocessing PROCEDURE'S effectiveness has been VERIFIED through appropriate scientific methods by the MANUFACTURER;

b) the reliability of the documented reprocessing PROCEDURES has been VERIFIED in practice through appropriate quality assurance measures by the RESPONSIBLE ORGANIZATION carrying out the reprocessing PROCEDURES.

When selecting and evaluating the reprocessing PROCEDURES, the MANUFACTURER should consider:

— the amount and type of pathogenic microorganisms expected to contaminate the HUMIDIFIER, ACCESSORIES or parts;

— the RISK for the pathogenic microorganisms to be transmitted to the PATIENT, OPERATOR or other persons;

— the microorganism's resistance to the recommended reprocessing PROCEDURES.

The RISKS posed by a reprocessed HUMIDIFIER, ACCESSORIES or parts are determined by the following factors:

a) undesired effects, which can result from:

    — the previous use;

    — the previous reprocessing PROCESSES;

    — transportation and storage;

b) the RISKS from subsequent uses, such as the following:

    — residues from the previous use (such as secretions, other body fluids, and drugs);

    — residues from the previous reprocessing PROCESSES (such as cleaning agents, disinfectants and other substances, including their reaction products);

    — changes of physical, chemical or functional properties of the device;

    — changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints);

c) the RISK of transmission of any pathogenic microorganisms.

When considering the suitability of the reprocessing PROCESS and the feasibility of the reprocessing PROCESS for the HUMIDIFIER, ACCESSORIES or parts, the MANUFACTURER should consider the following points:

— the RISKS involved in the reprocessing PROCESS;

— the cost effectiveness of the reprocessing PROCESS;

— the practicability of the reprocessing PROCESS;

— the availability of the cleaning equipment and the cleaning agents specified in the reprocessing PROCESS;

— the efficiency of the reprocessing PROCESS;

— the reproducibility of the reprocessing PROCESS;

— quality management requirements of the reprocessing PROCESS;

— the environmental impact of the reprocessing PROCESS and the disposal of the HUMIDIFIER, ACCESSORIES or parts.

The MANUFACTURER should VERIFY all cleaning agents and reprocessing PROCEDURES used with regard to their suitability and repeatability with the HUMIDIFIER, ACCESSORIES or parts, depending on the type of use.

The RESPONSIBLE ORGANIZATION should VERIFY that manual cleaning and disinfection of the HUMIDIFIER, ACCESSORIES or parts are always carried out in accordance with the PROCEDURES specified in the ACCOMPANYING DOCUMENT.

The MANUFACTURER should specify VALIDATED automated cleaning and disinfection PROCEDURES. If they are not followed, the effectiveness of the cleaning and disinfection cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of cleaning agents and disinfectants and residence time.

To ensure the reproducibility of automated reprocessing PROCEDURES, tests should be carried out on a regular basis.

The MANUFACTURER should ensure that the specified disinfection PROCEDURES are VERIFIED to be bactericidal, fungicidal and virucidal so that the cleaned and disinfected HUMIDIFIER, ACCESSORIES or parts do not pose an unacceptable RISK of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually comes in contact with the next PATIENT, OPERATOR or other person.

Effective disinfection requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

Following any reprocessing PROCEDURE, safety and functional testing of the HUMIDIFIER and ACCESSORIES (as specified by the MANUFACTURER'S instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the HUMIDIFIER.

The extent and type of the tests depends on the HUMIDIFIER, ACCESSORY or part and these need to be defined in the ACCOMPANYING DOCUMENT.

Subclause 201.12.1.101 — HUMIDIFICATION OUTPUT

HUMIDIFIERS can be used with PATIENTS whose upper airways have been bypassed by a tracheostomy or tracheal tube (invasive ventilation). The upper airway provides the major

portion of the heat and moisture supplied to the alveoli. When the upper airways are bypassed, the HUMIDIFIER needs to supply this missing heat and moisture. The humidity in the trachea during normal respiration can range from 36 mg/l to 40 mg/l. This figure is for a healthy PATIENT and still requires healthy functioning airways to further condition the gas to reach BTPS — adding moisture and raising the temperature to achieve 37 °C/44mg/l for alveolar conditions.

Physiological humidity levels (37 °C/44 mg/l) prevent depletion of moisture from the mucociliary transport system and maintain normal mucus clearance. When the airway is exposed to low levels of humidity, the aqueous layer decreases, the mucus layer thickens, and cilia beat slows[24]. This reduces the airway defence mechanism and increases the RISK of respiratory infection[25].

If the PATIENT has compromised airways as is typical of a long-term intubated PATIENT, then they should be supplied with breathing gasses as close to 37°C/44mg/l (alveolar conditions) as possible in order to minimize the extra load placed on the remaining airways.

Since the optimal moisture level below the carina is 44 mg/l (100 % RH at 37 °C), a moisture content of more than 33 mg/l, and up to 44 mg/l at the PATIENT-CONNECTION PORT, is required to prevent the drying out of secretions in the artificial airway.

The minimum temperature of gas able to hold 33 mg/l of water at BTPS conditions is 32,2°C (refer to Table AA.1). However, this document refers to the conditions of gas delivered to the PATIENT-CONNECTION PORT. There will be some temperature drop across the tracheal tube connector and tracheal tube, which are exposed to the ambient air. Typically, the temperature will drop a few degrees Celsius along the length of a tracheal tube connector.

The requirement is for a minimum of 32,2 °C delivered to the lower trachea, so the gas can contain 33 mg/l of water at BTPS conditions. Therefore, for invasive ventilation, the temperature at the PATIENT-CONNECTION PORT should be at least 34 °C to allow for a minimum of a 2 °C temperature drop along any catheter mount.

A tracheal tube does not increase the temperature and humidity as efficiently as the upper respiratory tract. As a tracheal tube limits the warming and humidification of gas as it passes into the PATIENT airway, the temperature and humidity requirements of the gas are higher at the PATIENT-CONNECTION PORT to accommodate for the lack of gas conditioning. The measurement of gas temperature and humidity as it enters the intubated PATIENT and travels down the tracheal tube has shown that if the gas is not warmed and humidified to BTPS prior to entering the PATIENT, then further warming and humidification of the gas is required by the lower airway. However, the lower airway in healthy non-intubated person contributes little to gas conditioning[25]. Thus, in striving for physiological humidity levels at the carina (37°C/44mg/l) in PATIENTS whose upper airways have been bypassed (invasive ventilation), the HUMIDIFIER needs to be capable of producing a HUMIDIFICATION OUTPUT of at least 33 mg/l at the PATIENT-CONNECTION PORT.

HUMIDIFIERS can also be used in PATIENTS whose upper airways have not been bypassed (non-invasive ventilation, nasal high flow therapy, sleep apnoea continuous positive airway pressure or CPAP treatment). Adequacy of ventilation is dependent on providing sufficient airflow to maintain a pressure gradient from the interface to the PATIENT airways. The nasal mucosa has considerable capacity to heat and humidify inspired air, but this capacity can be overwhelmed at high flowrates during ventilation. These conditions provoke mucosal hypertonicity, nasal congestion and increased nasal resistance.

During normal breathing inspired air is warmed and humidified in the upper airways to 31 °C, 30,8 mg/l BTPS, by the time it reaches in the pharynx. By heating and humidifying the non-

invasive gas flow to the same level which occurs naturally in the nasopharynx, the effects of drying can be prevented, increasing PATIENT comfort and tolerance to therapy[26][27][28].

Nasal congestion, dry nose and dry throat are common in PATIENTS requiring non-invasive ventilation and sleep apnoea CPAP treatment. High pressures and flows provoke changes in the nasal cell structure, mucosal hypertonicity, nasal congestion, nasal discharge, and increased nasal resistance[28][29][30]. This airway drying effect is amplified with oral breathing, mask leak and unidirectional flow associated with nasal masks and mouth leak[32][33].

Increased nasal resistance is attenuated with humidity levels of 21 mg/l and minimized with >30 mg/l. Comfort data suggests that humidity levels above 15 mg/l increases PATIENT tolerance and 30 mg/l reduces the feeling of oral dryness. Unheated pass-over humidification can achieve humidification levels of 7 mg/l to 12 mg/l. However, cold-pass-over does not achieve the improvement in respiration water loss or the increase in PATIENT compliance that can be achieved using heated humidification[25][26][29][30][31][32][33][34][35][36][37][38][39]. Thus, 12 mg/l should be seen as a minimum level of humidification for PATIENTS whose upper airways have not been bypassed.

All of the above discussion assumes a PATIENT at standard body temperature of 37 °C. For cases of intentional hypothermia or hyperthermia, the limits should be adjusted accordingly.

For an ACTIVE HME, the HUMIDIFICATION OUTPUT cannot be determined with the tests described in this document. The moisture loss test specified in ISO 9360-1[5] and ISO 9360-2[6] is more appropriate and can provide an indication of performance for an ACTIVE HME. Since an ACTIVE HME adds water, the tests of ISO 9360-1[5] and ISO 9360-2[6] might not indicate a moisture loss, but an addition of moisture. The moisture loss value and HUMIDIFICATION OUTPUT are not directly comparable.

Subclause 201.12.1.102 — SET TEMPERATURE accuracy and MONITORING EQUIPMENT

The displayed MEASURED GAS TEMPERATURE needs to be as accurate as practicable. The committee considered that an inaccuracy of less than 2 °C of the displayed MEASURED GAS TEMPERATURE does not compromise the clinical condition or the safety of the PATIENT. It is important that the OPERATOR is made promptly aware when the MEASURED GAS TEMPERATURE has exceeded the SET TEMPERATURE by more than an acceptable amount. The committee agreed that what constituted an acceptable amount could be left to the MANUFACTURER.

The over-temperature ALARM LIMIT is set at 43 °C. Additional information is found in the rationale for 201.13.1.101. Because of the ability of the airways to supply or absorb heat and moisture, this overshoot is required to not exceed an energy equivalent to air at 43 °C and 100 % RELATIVE HUMIDITY (a specific enthalpy 197 kJ/m^3 of dry air), averaged over 120 s. If the delivered gas energy exceeds a specific enthalpy of 197 kJ/m^3 of dry air) when averaged over 120 s under NORMAL CONDITION or SINGLE FAULT CONDITION, the HUMIDIFIER is required have a means to detect an extreme over-energy ALARM CONDITION.

Subclause 201.12.1.103 — MEASURED GAS TEMPERATURE MONITORING EQUIPMENT

For a HUMIDIFIER that displays the MEASURED GAS TEMPERATURE, the committee concluded that a range of 25 °C to 45 °C was the minimum that an OPERATOR required to operate the HUMIDIFIER. It should be very clear to the OPERATOR if the displayed MEASURED GAS TEMPERATURE is higher than 45 °C or lower than 25 °C.

A HUMIDIFIER controller, by its nature, continuously adjusts the components of the HUMIDIFICATION SYSTEM that affect the temperature of the humidified gas delivered to the PATIENT. It is normal, therefore, for the MEASURED GAS TEMPERATURE to cycle about the SET TEMPERATURE, but this is not

considered to be clinically significant providing the temperature is within ±2 °C of the SET TEMPERATURE when averaged over 5 min.

Subclause 201.12.4.101 — Thermal overshoot

The human airway has a very significant ability to absorb or deliver heat and moisture. Reference the common practice of sitting in a sauna without HARM to the respiratory track[40]. Fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract[41]. A more recent study reported tolerance of inspired gas temperatures of 46,9 °C to 49,3 °C, 100 % RH (256 kJ/m^3) for 49 min[42].

Taking into account the enthalpy of inspired gas that has been shown to be tolerated without causing thermal injury to the human airways and the very short exposure times of thermal overshoot from a heated HUMIDIFIER in clinical practice, the delivered gas energy limit of 197 kJ/m^3 of dry gas when averaged over 120 s can be used.

When considering gas mixtures other than oxygen/air, the following should be observed. Given that most of the energy is contained in the water vapour, the equivalent of air at 43 °C, 100 % RH is the maximum enthalpy that should be allowed. This has a specific volume of 0,978 6 m^3/kg of dry air and an enthalpy content of 197 kJ/m^3 of dry air. Assuming the volume breathed by the PATIENT is the same, whatever gas mixture is used, then the safe enthalpy limit is 197 kJ/m^3 of dry gas. This enthalpy per unit volume gives a more relevant measure of the energy delivered to the PATIENT.

Sustained DELIVERED GAS TEMPERATURES above 41 °C represent a potential thermal HAZARD to the PATIENT. Although it is rarely needed for PATIENT care, a sustained DELIVERED GAS TEMPERATURE of 41 °C at any level of saturation is not a thermal HAZARD to the PATIENT. DELIVERED GAS TEMPERATURES above 41 °C, depending on the combination of gas temperature, level of saturation and PATIENT exposure time, can be hazardous.

Studies to measure the relative importance of exposure time and temperature in causing cutaneous burns determined that surface temperatures of at least 44 °C and 6 h exposure were required to cause irreversible damage to epidermal cells[43]. This is confirmed by studies conducted by the US Navy Medical Research and Development Command[41], which concluded that fully saturated gas at 45 °C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.

Gas at body temperature and fully saturated (37 °C and 100 % RH) will not transfer thermal energy to or from the PATIENT with a normal body temperature of 37 °C. Dry gas at body temperature (37 °C and 0 % RH) will draw heat away through evaporation. Gas at 41 °C and fully saturated has the capacity to deliver less than 181,3 kJ/m^3 of dry gas breathed by the PATIENT. To protect the PATIENT from thermal injury, heating of the HUMIDIFIER is interrupted if the DELIVERED GAS TEMPERATURE exceeds 43 °C. A thermal overshoot, not to exceed energy equal to air at 43 °C and 100 % RH averaged over 120 s (197 kJ/m^3 of dry gas), is inconsequential to the PATIENT and is permitted to simplify construction of the HUMIDIFIER.

It is therefore important that the OPERATOR be provided with a continuous display of the MEASURED GAS TEMPERATURE, and that the HUMIDIFIER automatically interrupts heating and activates the over-temperature ALARM CONDITION when the MEASURED GAS TEMPERATURE exceeds 43 °C.

The testing conditions required in 201.12.4.101 are important to ensure that large shifts in flowrates do not result in excessive overshoots of high-energy gases being delivered to the PATIENT.

Subclause 201.13.1.101 — Additional specific HAZARDOUS SITUATIONS

Excessive liquid output could cause PATIENT injury and an accumulation of water in the BREATHING TUBE.

Subclause 201.13.102 — Independence of HUMIDIFICATION control function and related RISK CONTROL measures

This requirement prevents the use of a monitoring device to control an actuator that would lead to an undetected malfunction of the actuator in case of monitoring failure.

Subclause 201.101.1 — General

Non-standard BREATHING SYSTEM connectors can represent an unacceptable RISK as attempts are made to fit a standard BREATHING SYSTEM to a ventilator or HUMIDIFIER in an emergency situation. Non-standard BREATHING SYSTEM connectors can cause leaks if used with similar but not compatible connectors.

Subclause 201.101.4 — ACCESSORY port

The use of Luer taper or Luer-lock connectors complying with ISO 594-1 or ISO 594-2 are not permitted for use in a BREATHING SYSTEM as there are several case reports of accidental connection with intravenous fluids and parenteral and enteral feeding solutions causing serious morbidity and mortality due to aspiration of these foreign substances into the lungs.

Subclause 201.101.8.2 — Leakage

60 cm H_2O is the pressure currently proposed for testing leaks in ISO 5367. 5 ml/min leakage from the engaged sensor or mating port is 10 % of the total allowable leakage, for a whole BREATHING SYSTEM, in ISO 5367.

Subclause 201.102.1 — General

As safe use depends on the interaction of the HUMIDIFIER with ACCESSORIES, this document sets total-system performance requirements referenced to the PATIENT-CONNECTION PORT. Therefore, total system performance requirements are applicable to both MANUFACTURERS of HUMIDIFIERS and BREATHING TUBES intended for use with a HUMIDIFIER (both HEATED BREATHING TUBES and non-heated BREATHING TUBES). The HUMIDIFIER with ACCESSORIES should have a means of reducing condensate in the BREATHING TUBES.

EXAMPLE Heating the BREATHING TUBE or the placement of water traps.

It is the responsibility of the MANUFACTURER of a BREATHING SYSTEM, its parts or ACCESSORIES to VERIFY that their product complies with the requirements of this document.

BREATHING TUBES up to the PATIENT-CONNECTION PORT form part of the total system performance requirements. MANUFACTURERS of BREATHING TUBES need to ensure that total-system performance requirements are met by testing the BREATHING TUBES (both heated and non-heated) with the recommended HUMIDIFIER.

Subclause 201.102.3 — BREATHING TUBES

BREATHING TUBES have been reported to collapse on bending, occlude and perforate due to the heat generated by HUMIDIFIERS and supplemental electrical heating. It is believed that a BREATHING TUBE which is tested to meet the requirements of this document, and which does not kink, occlude and perforate during these tests, can provide BASIC SAFETY and ESSENTIAL PERFORMANCE in clinical use.

Subclause 201.104.1 — General

The connections between a HUMIDIFIER and the source of breathing gas, and the HEATED BREATHING TUBE CONTROLLER and a heater within a BREATHING TUBE, are FUNCTIONAL CONNECTIONS. In the event of disruption of these FUNCTIONAL CONNECTIONS, or failure of the connected equipment, the HUMIDIFIER is required to maintain ESSENTIAL PERFORMANCE, as indicated in Table 201.101. For a CATEGORY 1 HUMIDIFIER, loss of HUMIDIFICATION OUTPUT is acceptable provided an ALARM CONDITION is created. For a CATEGORY 2 HUMIDIFIER, the ALARM CONDITION is not required. In all cases, BASIC SAFETY is required to be maintained.

Subclause 201.104.2 — Connection to electronic health record

Electronic documentation of PATIENT care interventions is rapidly becoming the standard of care. The primary motivations are to improve the quality of care for an individual PATIENT through accurate and complete documentation, and to improve the completeness and accuracy of aggregated data to facilitate continuous quality improvement. Providing remote supervisory capability is rapidly becoming the standard of care in the HOME HEALTHCARE ENVIRONMENT.

Subclause 201.104.3 — Connection to DISTRIBUTED ALARM SYSTEM

PATIENTS are not always located near enough to the OPERATOR to ensure that ALARM SIGNALS coming from the PATIENT'S room can be heard. It is reasonably foreseeable that some rooms of a PATIENT'S home, limited care facility or healthcare facility are out of earshot of other rooms. As a result, it is recommended for a HUMIDIFIER be equipped with a means to connect to a DISTRIBUTED ALARM SYSTEM that can provide additional ALARM SIGNAL presentation points. A DISTRIBUTED ALARM SYSTEM facilitates delivery of ALARM SIGNALS to other rooms where the OPERATOR might be located, thereby permitting a timely response and intervention to support PATIENT care.

Subclause 202.8.1.101 — Additional general requirements

It is not the intent of the committee to require that the IMMUNITY tests be performed multiple times at several HUMIDIFICATION OUTPUTS, but that the MANUFACTURER should determine which HUMIDIFICATION OUTPUT represents the worst case for a given IMMUNITY test and use those conditions.

Commercially available hygrometers can be used to monitor changes in the HUMIDIFICATION OUTPUT as acceptance criteria following the specific tests required by this document to demonstrate the maintenance of ESSENTIAL PERFORMANCE.

Subclause 208.6.8.4.101 — Additional requirements for termination of ALARM SIGNAL inactivation

Permitting very long pauses of ALARM SIGNALS can be hazardous for the PATIENT since the OPERATOR will not be notified of the existence of an ALARM CONDITION. However, PATIENT management often requires PROCEDURES that can be disrupted by auditory ALARM SIGNALS. Therefore, extending AUDIO PAUSED by OPERATOR action is useful to prevent the HUMIDIFIER from disturbing the OPERATOR or others in the vicinity.

HUMIDIFIERS should be equipped with an AUDIO PAUSED capability that permits the OPERATOR to pause the ALARM SIGNALS prior to the creation of an ALARM CONDITION. Such a capability permits the OPERATOR to minimize nuisance auditory ALARM SIGNALS.

Annex BB — Determination of the accuracy of the displayed MEASURED GAS TEMPERATURE

It is difficult to measure temperature at precisely the same location as the HUMIDIFIER'S temperature sensor without modifying the gas flowrate, and hence, the thermal transfer characteristics from the gas to the HUMIDIFIER'S temperature sensor. The object of the test is to

measure temperature on either side of the HUMIDIFIER'S temperature sensor and interpolate the temperature to the site under test. Temperature drop in the circuit can be nonlinear. Hence, the objective is to place the standard temperature sensors as close as possible to the HUMIDIFIER'S temperature sensor, but with minimal disruption of gas flow patterns.

Annex CC — Determination of the HUMIDIFICATION OUTPUT

The HUMIDIFICATION OUTPUT is defined as the mass of water vapour per unit volume of gas (mg/l) at BTPS reference conditions, which is physiologically more appropriate than other reference conditions.

Commercially available hygrometers do not have the necessary speed of response to provide consistent and correct results when operated in the non-isothermal environment of the BREATHING SYSTEM. Therefore, the use of such instruments should be restricted to constant-flow humidity measurements. However, the use of such instruments is suitable to VERIFY the maintenance of ESSENTIAL PERFORMANCE during all of the tests of this document except the determination of the HUMIDIFICATION OUTPUT required in 201.12.1.101 for ventilated gas flow conditions, which are not constant and for which the time response of the instrument is too slow to respond to the rapid changes in the ventilated flow waveform.

The use of a dew point hygrometer requires a conversion from the specified units of mg/l (reference BTPS) to equivalent values for dew point. See Table AA.1.

Table AA.1 — Equivalent dew point for minimum required HUMIDIFICATION OUTPUT

HUMIDIFIER classification	Absolute humidity under BTPS conditions mg/l	Equivalent dew point °C
Category 1	33	32,2
Category 2	12	15,9

Annex DD — Specific enthalpy calculations

Formula (DD.2)

The total enthalpy calculation comes from a logical understanding of the fundamental properties of ideal gases. Amagat's Law tells us that the total volume is the sum of the partial volumes. Therefore, the total enthalpy is the sum of the enthalpies calculated for each gas component (i.e. the sum of the dry gas enthalpy and the water vapour enthalpy). It is observed that Formula (DD.2) has the same form as that of ISO 8185[2], but with the result multiplied by density to give the desired volumetric reference units. This formula can also be found in standard reference books[44].

Annex FF — Standard temperature sensor

The standard temperature sensor includes an additional copper thermal mass to effect an averaging of temperature across the circuit, minimize effects of condensation forming on the sensor, reduce effects of precise positioning of the sensor, increase thermal transfer to the sensor, minimize the stem effect and ensure a stable temperature measurement.

The measuring of any temperature in a non-isothermal situation is difficult. It is not a matter of just using a thermometer. Energy input, energy output, thermal conductivities all have to be taken into account. Good, calibrated temperature measuring instruments, when used to measure flowing gas temperature in a narrow tube, can have readings that differ by up to 10 °C from each

other. The method prescribed in this document is an attempt to limit the variability, and define a standard temperature-measuring method, to allow comparison and repeatability.

Thermistors are chosen as the sensing element as they are small, readily available, have low drift, have a significant output signal over the temperatures of interest and are easily interfaced to simple circuits.

The particular values and dimensions of the thermistor are specified to match commonly available commercial devices and are to standardize the thermal loss and stem effect of the constructed sensor.

When placing the thermistor sensor in a measuring circuit, care must be taken to ensure that the current used does not cause significant self-heating of the thermistor.

A good 4 1/2 digit (or better) multimeter can be used to measure the resistance directly but care needs to be taken to be sure that the currents the meter generates to make such measurements do not cause significant self-heating.

Annex BB
(normative)

* Determination of the accuracy of the displayed MEASURED GAS TEMPERATURE

BB.1 Test preparation

Confirm the accuracy of the displayed MEASURED GAS TEMPERATURE by introducing two standard temperature sensors, as defined in Annex FF, into the HUMIDIFIER and ACCESSORIES that are configured in accordance with the ACCOMPANYING DOCUMENTS. The configuration of the sensors is shown in Figure BB.1.

If necessary, add extension tubing so that ambient drafts and temperatures do not unduly influence the sensors. Such tubing should be of the same diameter as the BREATHING TUBES and long enough so that all sensors are located at a distance from ambient drafts equal to at least 10 times the BREATHING TUBE diameter.

The distances from the normal location of the HUMIDIFIER'S temperature sensor to the location of the standard temperature sensors (distance *l* in Figure BB.1) shall be equal and shall measure from 20 mm to 30 mm.

Key

1 normal location

2 seal

3 standard temperature sensor

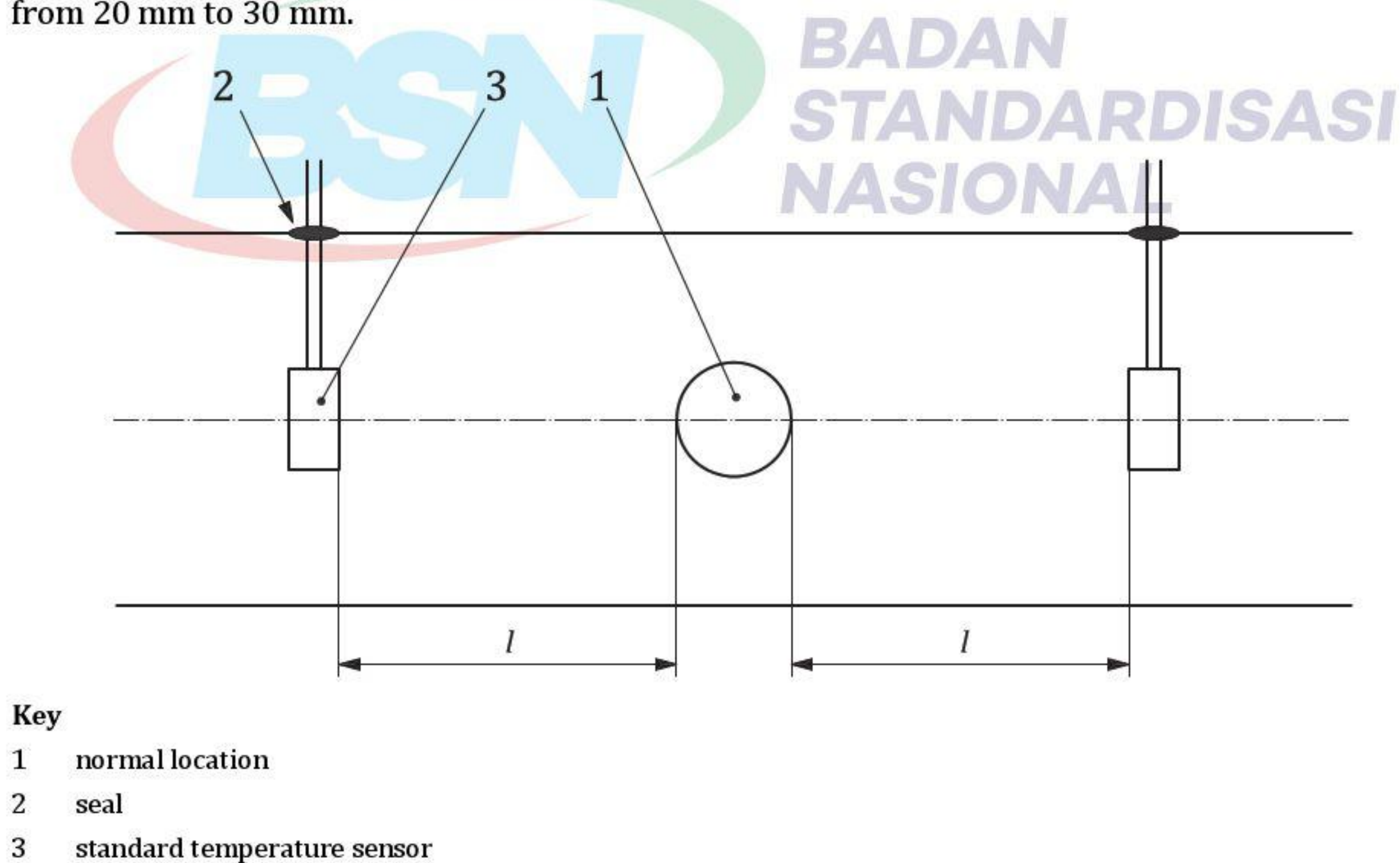



Figure BB.1 — Configuration for displayed temperature accuracy test

BB.2 Test PROCEDURE

Carry out testing as follows.

a) *Sample the temperature at least every 2 s.*

b) *Operate the* HUMIDIFIER *over the flowrate range indicated in the* ACCOMPANYING DOCUMENTS.

c) *Set the minimum* SET TEMPERATURE *and confirm that the* MEASURED GAS TEMPERATURE *is within ±2 °C of the arithmetic mean of the two standard temperature sensors in a steady-state condition.*

d) *Change the* SET TEMPERATURE *from the minimum to the maximum setting.*

e) *Confirm that the* DISPLAYED GAS TEMPERATURE *is within ±2 °C of the arithmetic mean of the two standard temperature sensors in a steady-state condition for the maximum* SET TEMPERATURE.

Annex CC
(normative)

* Determination of the HUMIDIFICATION OUTPUT

CC.1 Principle

The HUMIDIFICATION OUTPUT is measured using the gravimetric method, which is a simple technique.

This test method uses dry input air, so any moisture in the output air has been added by the HUMIDIFIER. The volume of output air is normalized to the volume it would occupy under BTPS conditions.

CC.2 Test conditions

There are several practical considerations required to perform this test method in order to calculate the HUMIDIFICATION OUTPUT. As several different definitions of “standard conditions” exist, it is important to know the reference conditions for the flowmeter calibration.

Table CC.1 provides the most commonly encountered reference conditions and a corresponding correction factor to scale the volumetric flowrate reading referenced to standard conditions to a volumetric flowrate referenced to BTPS conditions as required to perform the gravimetric calculation.

Table CC.1 — Common reference conditions and their correction factors

Publishing entity	Standard conditions standard l/min	Scaling factor to BTPS l/min
NIST, ISO 10780	0 °C, 101,325 kPa	1,210
EPA, NIST	20 °C, 101,325 kPa	1,127
AMCA	21,1 °C, 101,325 kPa	1,123
NIST (US National Institute of Standards and Technology) EPA (US Environmental Protection Agency) AMCA (Air Movement and Control Association International)		

For a more precise conversion to BTPS, if independent accurate means of measuring ambient pressure and temperature are available, the conversion from V_{ATP} to V_{BTPS} is calculated using the following Formula (CC.1) based on the Ideal Gas Law assuming that the input gas is dry:

$$V_{BTPS} = V_{ATP} \times \frac{T_{body}}{T_{amb}} \times \frac{P_{amb}}{\left[P_{amb} - P_{v}\left(T_{body}\right)\right]} \quad \text{(CC.1)}$$

where

P_{amb} is the ambient pressure;

P_{v} (T_{body}) is the saturation vapour pressure at T_{body} (in K) as calculated using Formula (CC.2);

V_{ATP} is the volume at ATP (ambient temperature, pressure) conditions;

T_{body} is 310 °K;

T_{amb} is the temperature of the delivered gas.

$$P_v(T_{body}) = 10^{30,590\,51 - 8,2\lg T_h + 2,480\,4 \times 10^{-3} \times T_h - \left(\frac{3\,142,31}{T_h}\right)} \quad \text{(CC.2)}$$

NOTE When T_{amb} is equal to T_{body}, P_v (T_{body}) equals 6,270 987 kPa.

CC.3 Apparatus

The following items shall be utilized with measurement apparatus and for sufficient duration such that a total measurement accuracy of ±1 mg/l is achieved:

a) the HUMIDIFIER under test with its ACCESSORIES as indicated in the instructions for use;

b) a weight scale;

c) a timer;

d) a flowmeter;

NOTE 1 Most readily available commercial air flowmeters are calibrated for dry gas and it is therefore desirable to measure the gas flow on the dry side (i.e. the input to the HUMIDIFIER).

e) a standard temperature sensor as defined in Annex FF.

f) a gas source

NOTE 2 Additional information is provided in 201.5.

CC.4 PROCEDURE

The gravimetric method HUMIDIFICATION OUTPUT is determined as follows.

a) Configure the HUMIDIFIER with its ACCESSORIES as indicated in the instructions for use.

b) Install the standard temperature sensor at a site representing the DELIVERED GAS TEMPERATURE. Call this temperature T_2 (°C).

c) If necessary, add extension tubing such that ambient drafts and temperatures do not unduly influence sensors. Ensure that the extension tubing is of equal diameter to the BREATHING TUBE and of length such that all sensors are located at a distance from ambient drafts equal to at least 10 times the BREATHING TUBE diameter.

d) Confirm that the ambient temperature of the HUMIDIFIER and ACCESSORIES are within the range of 17 °C to 23 °C. Measure the input gas temperature and call this temperature T_1 (°C). Confirm that the inlet gas temperature is within the RATED ambient temperature range of the HUMIDIFIER.

e) Arrange relative elevations of the HUMIDIFIER, BREATHING TUBE and HUMIDIFICATION CHAMBER, as applicable, such that:

— *Condensation that does not represent humidification reaching the* PATIENT *(e.g. condensation in the inspiratory limb) does not leave the humidification system and is included in m_1 (the mass of the* HUMIDIFIER*), its contents and the recommended* BREATHING TUBE *as defined in h).*

— *Condensation that represents humidification reaching the* PATIENT *(e.g. condensation occurring in the instrumental dead space) leaves the* HUMIDIFIER *and is not included in m_1 [see h)].*

f) *Connect the* HUMIDIFIER *to the gas source.*

g) *Set the gas flowrate with the flowmeter to the maximum* RATED *flowrate ±5 % and turn the* HUMIDIFIER *on at its maximum output setting. Confirm that at least 2 h have elapsed to ensure that the error due to the warm-up time of the* HUMIDIFIER *is minimized.*

h) *Turn off the* HUMIDIFIER*. Disconnect all* ACCESSORIES*, including the gas source, electrical connections and any extension tubing to remove any extraneous influences on the mass measurement. Weigh only the* HUMIDIFIER*, its contents and the recommended* BREATHING TUBE*; record this mass as m_0. This is the initial mass of the* HUMIDIFIER*.*

i) *Reconnect all* ACCESSORIES*.*

j) *Turn the* HUMIDIFIER *on and start the timer.*

k) *Record the start time as t_0 and maintain* OPERATOR *control settings throughout the test.*

l) *Stop the test when the measurement of the following quantities maintains a total measurement accuracy of ±1 mg/l:*

— *the* HUMIDIFIER *has used a sufficient quantity of the usable capacity of the* LIQUID CONTAINER*;*

— *the test is of sufficient duration.*

m) *Record the time as t_1 and record the duration of the test (t_1 - t_0).*

n) *Note the total elapsed time and convert to suitable time units with respect to the flowmeter reading.*

NOTE Special attention is drawn to the objective of a total measurement error of less than 1 mg/l. Measurement of time, temperature, especially flowrate and mass used, should be sufficiently accurate relative to the value of the quantity to maintain this objective. In practice, the mass and estimated output of the HUMIDIFIER *gives a guide as to the minimum duration of the test to maintain overall accuracy. An error analysis of the measurement apparatus and estimated results is strongly recommended as a guide.*

o) *Weigh the* HUMIDIFIER *at the end, and record the difference with respect to the starting mass.*

p) *Calculate the volume of gas humidified, V_{BTPS}, (referenced to* BTPS*) during the test using Formula (CC.3):*

$$V_{BTPS} = q_{SLPM} \times SF \times T_{DUR} \quad \text{(CC.3)}$$

where

q_{SLPM} is the flowrate of gas referenced to standard conditions;

SF is the scaling factor to BTPS (from Table CC.1);

T_{DUR} is the duration of the test.

q) *Calculate HUMIDIFICATION OUTPUT, H_{out}, (mg/l) using Formula (CC.4).*

$$H_{out} = \frac{\Delta m}{V_{BTPS}} \quad \text{(CC.4)}$$

where

Δm is the mass change of the HUMIDIFIER (in mg).

r) *Confirm that HUMIDIFICATION OUTPUT exceeds the value indicated in the instructions for use.*

s) *Repeat e) to r) with the ambient temperature at the HUMIDIFIER'S minimum RATED operating temperature ±1 °C.*

t) *Repeat e) to r) with the ambient temperature at the HUMIDIFIER'S maximum RATED operating temperature ±1 °C.*

u) *Repeat d) to t) at the HUMIDIFIER'S minimum RATED flowrate.*

Annex DD
(normative)

* Specific enthalpy calculations

DD.1 Calculation of specific enthalpy

The specific enthalpy, ΔH_s, of a moist gas is the energy released by the gas, per unit volume of dry gas, when cooled or heated at a constant pressure to 0 °C, inclusive of any contribution from water vapour and condensation, but exclusive of any contribution from water initially in a liquid form (such as water droplets). The volume referred to is the initial volume of the dry gas, and the preferred units of measurement for ΔH_s are kJ m^{-3}.

Table DD.1 lists symbols and values for properties used in the calculation of specific enthalpy.

Table DD.1 — Symbols and values for the calculation of specific enthalpy

Symbol	Value	Description	Reference
M_{wv}	18,0153 g mol^{-1}	Molecular weight of water vapour	[45]
M_{air}	28,9645 g mol^{-1}	Molecular weight of dry air	[45]
$c_{p,air}$	1,0051 kJ kg^{-1} K^{-1}	Constant pressure specific heat capacity of dry air	[46][47]
$c_{p,wv}$	1,8662 kJ kg^{-1} K^{-1}	Constant pressure specific heat capacity of water vapour	[46][47]
L_{wv}	2 501 kJ kg^{-1}	Latent heat of vaporization of water at 0 °C	[48]
R	8,31446 J K^{-1} mol^{-1}	Universal gas constant	—

Formulae for the saturation vapour pressure, P_{sat}, for water are given in Annex GG. The specific humidity of a gas, $h_s(T_d,P)$, (mass of water vapour per unit mass of dry air), is calculated using Formula (DD.1):

$$h_s\left(T_d,P\right)=\frac{M_{wv}}{M_{air}}\frac{P_{sat}\left(T_d\right)}{P-P_{sat}\left(T_d\right)} \tag{DD.1}$$

DD.2 Specific enthalpy measurement

To calculate the specific enthalpy of a gas, the temperature, T in °C, pressure, P in Pa, and dew point temperature, T_d in °C, needs to be known. The specific enthalpy limit in this document refers to the specific enthalpy of the delivered gas. Thus, the PROCEDURE outlined below is used to measure the specific enthalpy. Deviations may be made from this PROCEDURE if justified appropriately.

a) With a sampling period of no longer than 2 s, measure:

1) the DELIVERED GAS TEMPERATURE, T (i.e. at the PATIENT-CONNECTION PORT);

2) *the temperature of the gas at the* HUMIDIFICATION CHAMBER *outlet,* T_h*, and take* T_d *as the minimum of* T *and* T_h*;*

3) *the pressure of the delivered gas, or an appropriately assumed value (such as 101 325 Pa at sea level).*

b) *Calculate the specific enthalpy using Formula (DD.2) and Formula (DD.3) below.*

c) *Filter the specific enthalpy using a moving average with a 120 s window period.*

d) *Confirm that the filtered specific enthalpy does not exceed 197 kJ/m³ at any time.*

For 20 °C ≤ T_d ≤ 60 °C and 20 °C ≤ T ≤ 80 °C, the specific enthalpy of moist air, ΔH_s, is given by Formula (DD.2):

$$\Delta H_s = \rho_{air} \left[c_{p,air} T + h_s \left(T_d, P\right)\left(L_{wv} + c_{p,wv} T\right)\right] \qquad (\text{* DD.2})$$

where

$$\rho_{air} = \frac{M_{air} \left[P - P_{sat} \left(T_d \right) \right]}{R \left(T + 273{,}15 \right)} \qquad (\text{DD.3})$$

Formula (DD.3) divides the computation into two parts: the contribution to the enthalpy due to the dry air, and due to the water vapour. The enthalpy is first calculated per unit mass of dry air, and then scaled by the density of air (ρ_{air}) to be per unit volume of dry air. The contribution due to the dry air is simply $c_{p,air}T$. The contribution due to the water vapour is found by multiplying the specific humidity (kg of water vapour per kg of dry air) by the specific enthalpy per unit mass of water vapour, which is approximated by $L_{wv} + c_{p,wv}T$.

If the delivered gas is not moist air (e.g. humidified oxygen), appropriate values for M_{air} and $c_{p,air}$ are substituted (e.g. M_{O2} and $c_{p,O2}$).

Annex EE
(normative)

Removable temperature sensors and mating ports

EE.1 General

Interoperable temperature sensors and their mating ports are needed to ensure that BREATHING SYSTEMS and HUMIDIFERS are compatible. For PATIENT safety, the temperature sensor needs to be securely retained in a compatible mating port once inserted.

EE.2 Dimensional requirements for removable temperature sensors

a) Removable temperature sensors shall

1) meet the dimensional requirements of Figure EE.1, or

2) be sufficiently different that they cannot be interchanged with those that do meet these requirements.

b) Temperature sensor mating ports shall

3) meet the dimensional requirements of Figure EE.2, or

4) shall be sufficiently different that they cannot be interchanged with those that do meet these requirements.

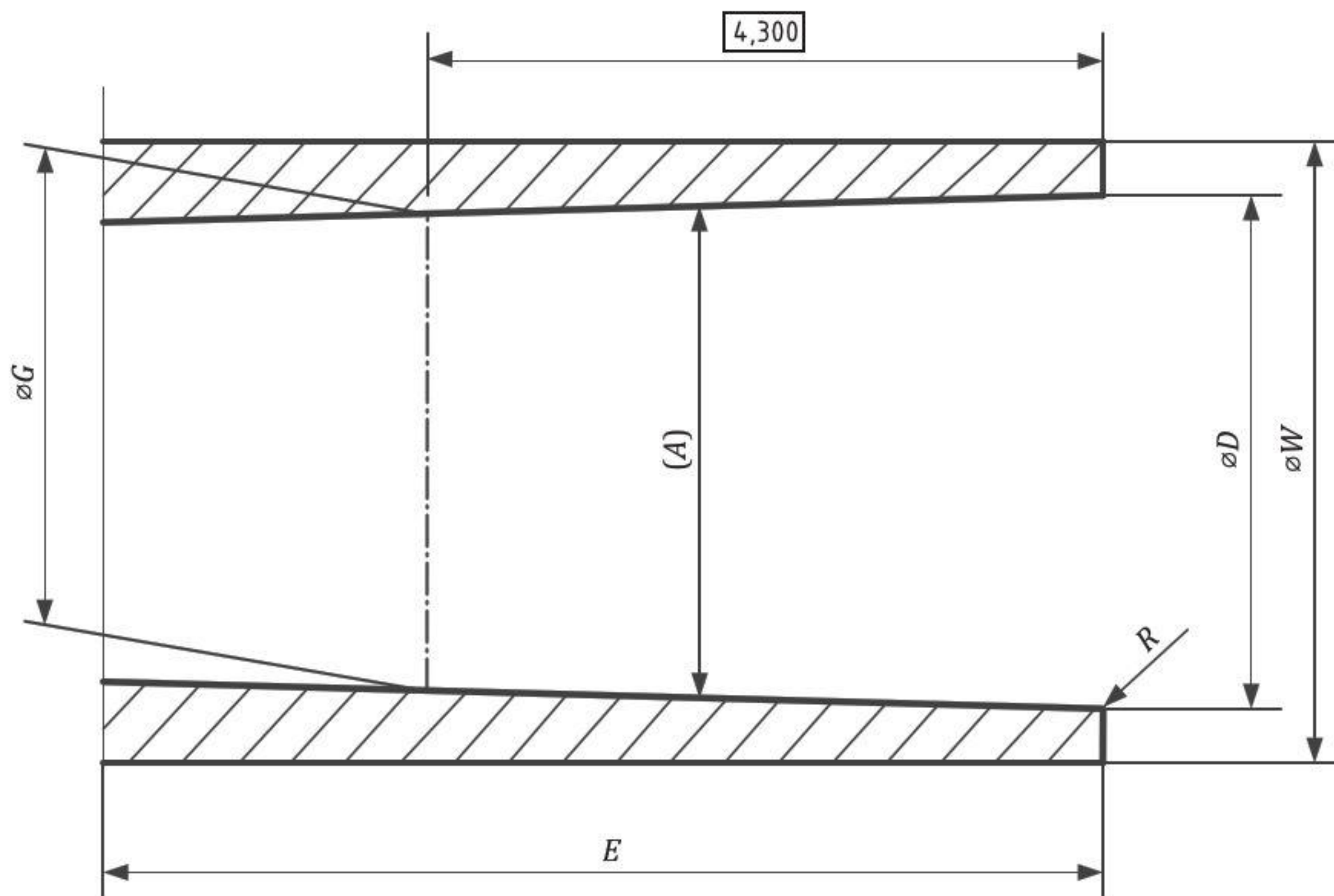
Dimensions in millimetres, unless otherwise indicated

NOTE Table EE.1 contains the dimensions for this figure.

Figure EE.1 — Removable temperature sensor port

Table EE.1 — Removable temperature sensor port dimensions

Dimensions in millimetres, unless otherwise indicated

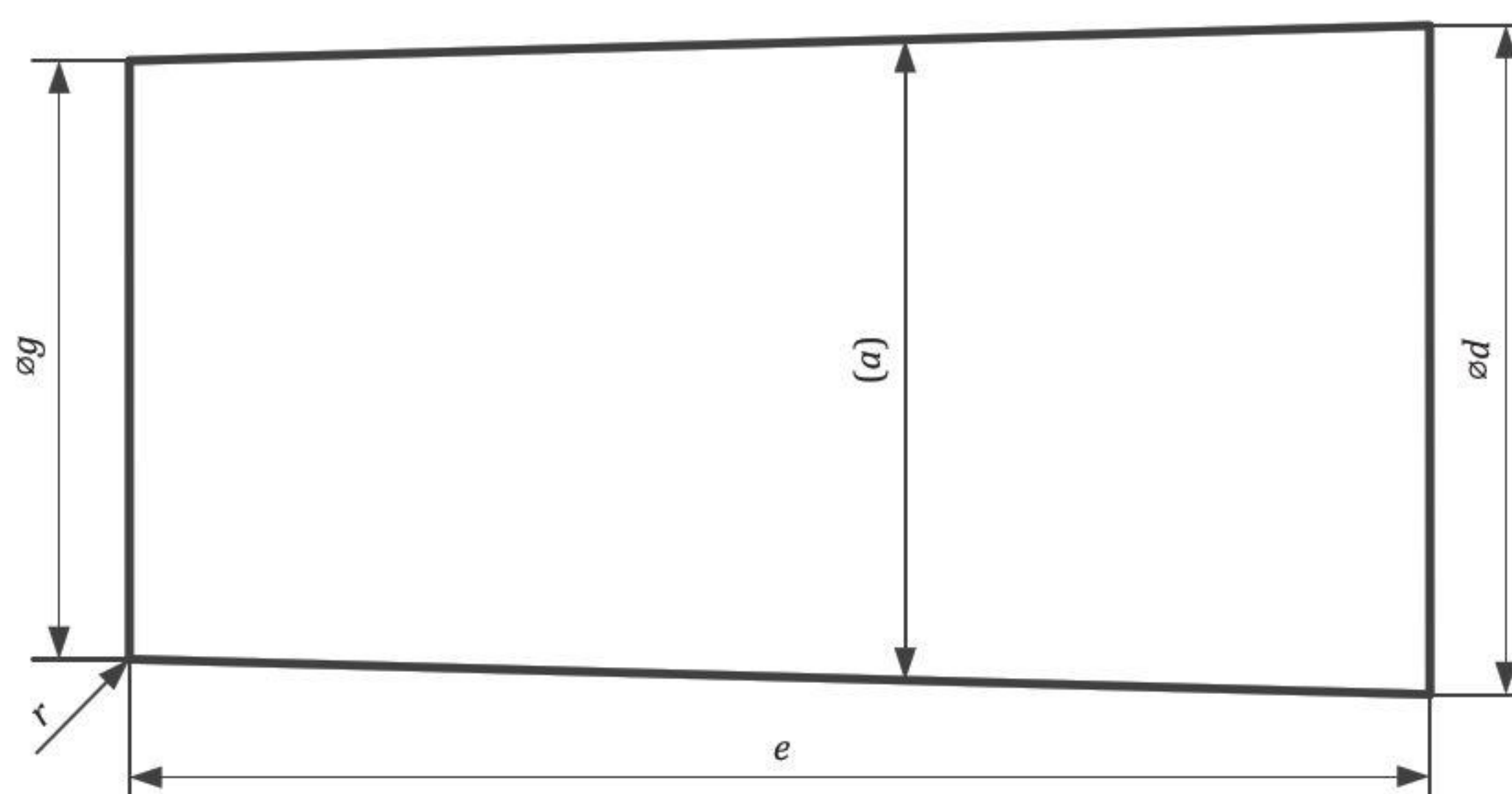
Removable temperature sensor port				
Reference	Designation	Dimension		
		Minimum	Nominal	Maximum
(A)	Conical taper of 1:40 included angle (degrees, reference)		(1,43)	
$ØD$	Inside diameter at the opening of the female taper	7,83	7,87	7,91
E	Depth of female taper	5,00	10,00	12,00
$ØG$	Inside diameter of the smaller end of the female taper at 4,3 mm from the opening of the female taper	7,72	7,76	7,80
$ØW$	Diameter of the smallest cylinder that encompasses the outside surfaces of the external features of the temperature sensor port	9,07	9,37	9,67
R	Radius or chamfer at the entrance of the female taper	0,00	0,25	0,50

NOTE Table EE.2 contains the dimensions for this figure.

Figure EE.2 — Removable temperature sensor dimensions

Table EE.2 — Removable temperature sensor dimensions

Dimensions in millimetres, unless otherwise indicated

Removable temperature sensor				
Reference	**Designation**	**Dimension**		
		Minimum	**Nominal**	**Maximum**
(a)	Conical taper of 1:40 included angle (degrees, reference)		(1,43°)	
$Ød$	Diameter at large end of the male taper	7,89	7,93	7,97
e	Depth of male taper	10,50	—	—
$Øg$	Diameter at small end of the male taper	7,56	7,60	7,64
r	Radius or chamfer at the small end of the male taper	0,00	0,25	0,50

EE.3 Test method for security of engagement of removable temperature sensors to mating ports

If a tapered conical connector is used for the removable temperature sensor, then it shall comply with the following separation force requirement.

Carry out security of engagement testing as follows.

a) *Condition removable temperature sensors and mating ports at (41 ± 2) °C and (95 ± 5) % RH for at least 1 h.*

b) *Engage the removable temperature sensor with the mating port in accordance with the* ACCOMPANYING DOCUMENTS.

c) *Condition the engaged components, without activation of any disengagement mechanism, for at least 1 h at the conditions specified in a).*

d) *Apply an axial separation force of (25 ± 2,5) N for 10 s at a rate not exceeding 20 N/s.*

e) *Confirm that sensor remains engaged.*

Annex FF
(normative)

* Standard temperature sensor

FF.1 Test preparation

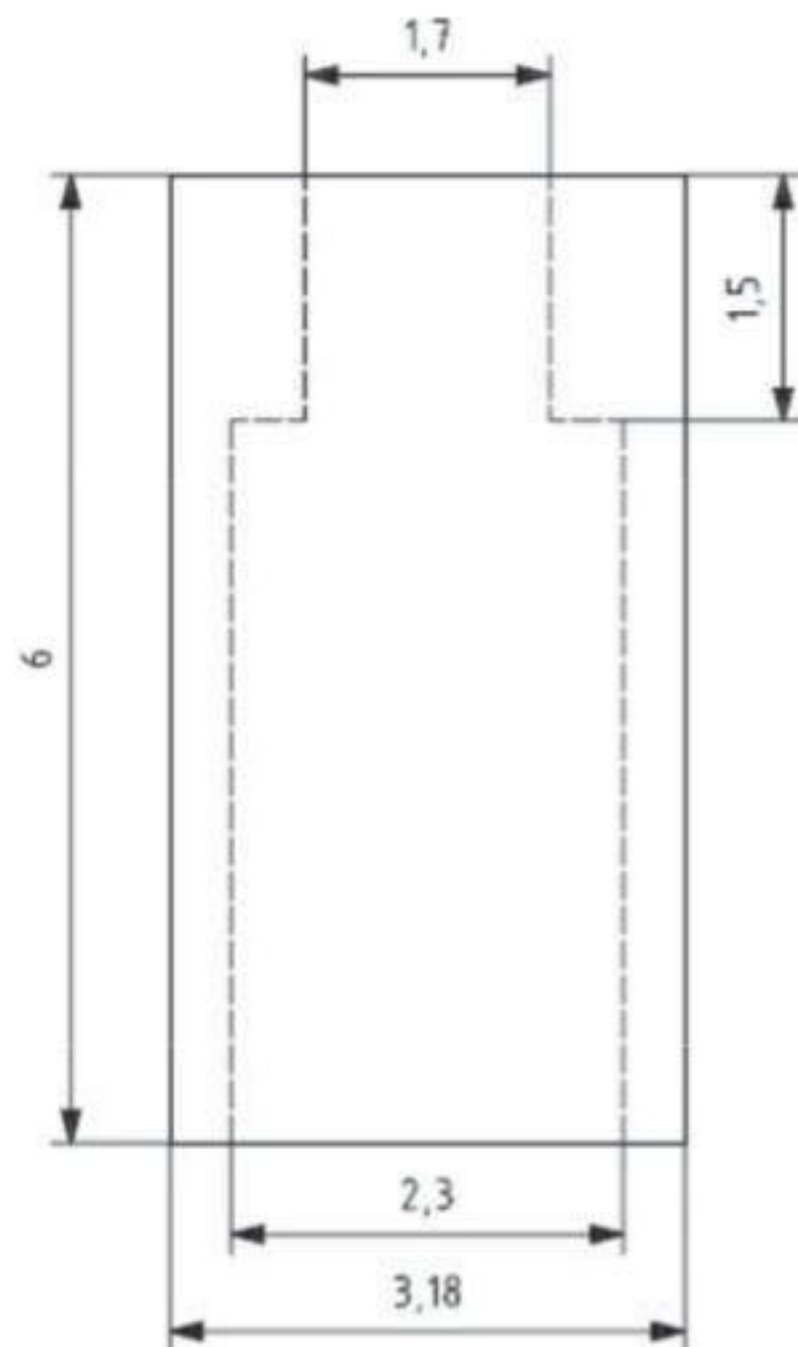
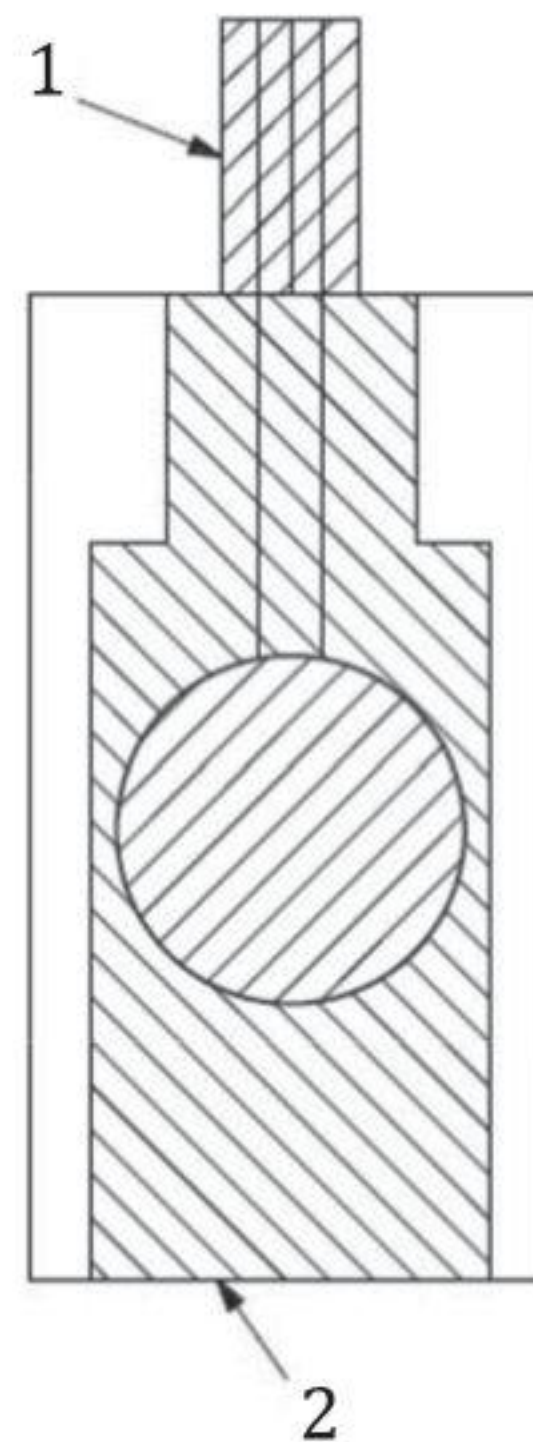
a) The standard temperature sensor shall meet the requirements indicated below. See also Figure FF.1.

b) A properly assembled standard temperature sensor shall have the following performance characteristics:

   1) time constant >0,5 s and <1,0 s for a step change of 22 °C to 37 °C in water at a flowrate of 1 m/s, and

   NOTE 1 This places bounds on the thermal conductivity of the constructed sensor.

   2) influenced by changes in ambient temperature of <0,01 °C per 1 °C.

   NOTE 2 This places a bound on the stem effect of the constructed sensor.

a) Sheath for standard temperature sensor

b) Standard temperature sensor construction

Key

1 electrical insulation on thermistor leads

2 thermally conductive paste or epoxy

Figure FF.1 — Standard temperature sensor

An example of the construction of such a sensor is as follows.

— A 6 mm length of 3,18 mm outside diameter copper tube. The inside diameter should be chosen to create sufficient clearance on the thermistor bead. Any other material with thermal conductivity >386 W/(m·K) with the dimensions given in Figure FF.1 is acceptable. A thermistor with an accuracy of ±0,2 °C from 25 °C to 45 °C (when in isothermal stirred air or water). The suppliers typically have thermistors of 2 252 Ohm resistance at 25°C. This is a suitable value for the accuracy the test requires.

— The electrical leads of the thermistor should be #32 gauge tinned copper wire, a minimum of 60 mm long (any other material with conductivity <180 W/(m K) is acceptable.

— The electrical leads of the thermistor should be sleeved to achieve electrical and thermal insulation. Plastic tubing achieves both aims, but any electrically insulating material with thermal conductivity <0,02 W/(m·K) is acceptable.

— The thermistor should be centralized in the copper tube, and the voids filled by a thermally conductive but electrically insulating compound (such as thermal heatsink paste or thermally conductive low-stress epoxy) having a thermal conductivity >0,183 W/(m·K).

NOTE 1 The copper sleeve is most easily manufactured from standard copper tube, diameter 3,18 mm (1/8 in). This gives a standard surface area and surface thermal conductivity to the constructed sensor.

NOTE 2 The temperature bead specified is readily available from many sources.[3]

NOTE 3 When placing the thermistor sensor in a measuring circuit, care needs be taken to ensure that the measuring current used does not cause significant self-heating of the thermistor.

[3] Compliant temperature beads (thermistors) are commercially available from sources including: Honeywell, Yellow Springs Instruments (YSI), Fenwal and Omega. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO or IEC of these products.

Annex GG
(informative)

Saturation vapour pressure

GG.1 Test preparation

The saturation vapour pressure and enhancement factor for water are used in the calculation of specific enthalpy in Annex DD. The saturation vapour pressure, P_{sat}, and enhancement factor, f, for water are given by Formula (GG.1) and Formula (GG.2) respectively[49].

$$P_{sat}(T) = (611{,}21) \times e^{\left(18{,}678 - \frac{T}{234{,}5}\right)\left(\frac{T}{T+257{,}154}\right)} \qquad \text{(GG.1)}$$

$$f(T,P) = 1{,}000\,72 + (P)\,[3{,}2 \cdot 10^{-8} + (5{,}9 \cdot 10^{-12})(T^2)] \qquad \text{(GG.2)}$$

where

T is the temperature of the gas in °C;

P is the atmospheric pressure in Pa.

To use the enhancement factor, multiply Formula (GG.1) by Formula (GG.2) for all enthalpy or humidity calculations using P_{sat} (see Annex CC and Annex DD).

The coefficients for Formula (GG.1) (saturation vapour pressure) and Formula (GG.2) (enhancement factor for water) were taken from Reference [50].

Annex HH
(informative)

Reference to the essential principles of safety and performance of medical devices in accordance with ISO 16142-1:2016[7]

This document has been prepared to support the essential principles of safety and performance of a CLINICAL THERMOMETER as a medical device according to ISO 16142-1:2016[7]. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO 16142-1:2016[7]. Other means are possible. Table HH.1 maps the clauses and subclauses of this document with the essential principles of ISO 16142-1:2016.

Table HH.1 — Correspondence between the essential principles and this document

Essential principle of ISO 16142-1:2016[7]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
1	all	The part relating to manufacturing is not addressed.
a)	206	
b)	206	
2		The part relating to manufacturing is not addressed.
a)	all	
b)	201.4	The part relating to manufacturing is not addressed.
c)	201.1.3, 201.7	
d)	201.7	
3	all	The part relating to manufacturing is not addressed.
4	all	
5	201.1.3, 201.4, 201.15	
6	201.4	
8.1	—	
a)	201.11	
b)	201.4, 201.11	
c)	201.9, 201.15	
8.2	201.11.7	

Table HH.1 *(continued)*

Essential principle of ISO 16142-1:2016[7]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
8.3	201.11	
8.4	201.11.7	
8.5	201.11.6.2	The part relating to ingress is not addressed.
9.1	201.11.6.6	
a)	201.11.6.6	
b)	201.11.6.6	
c)	201.11.6.6	
12.1	201.7, 201.14, 201.16, 201.101, 201.102, 201.104	
12.2	—	
a)	206	
b)	206	
c)	201.5, 202, 211	
d)	201.11	
e)	201.14, 201.16	
f)	201.11	
g)	202	
12.4	201.11	
12.5	201.7, 201.8	
12.6	201.1.3	
13.1	201.12.1	
13.2	201.7	
13.3	201.7, 201.12.1, 206, 208	
13.4	201.7	
15.1	201.14	
15.2	201.14	
16.1	201.4, 201.13	
16.5	202	
16.6	202	
16.7	201.8	
17.1	201.9, 211	

Table HH.1 *(continued)*

Essential principle of ISO 16142-1:2016[7]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
17.2	201.9	
17.3	201.9	
17.4	201.8, 201.15, 201.101	
17.5	201.15, 201.101, 201.102, 201.103	
17.6	201.11	
18.1	201.12	
18.2	201.12, 201.13.1.101, 201.13.102	
19.1	201.7	
19.2	201.7, 206, 211	
20.1	211	
20.2	206	
20.3	201.7.9.2.8.101	
21.1	201.7	
21.2	201.7	
21.3	201.7	
21.4	201.7.2.3, 201.7.2.13.101, 201.7.2.17.101, 201.8, 201.9, 201.11.7	
21.5	—	
a)	201.7	The part relating to authorized representative is not addressed.
b)	201.7, 201.7.2.17.101 a)	
f)	201.7	
i)	201.7.2.101 b), 211	
j)	201.7.2.101 b), 211	
k)	201.7.2.101 c)	
l)	201.7	
m)	201.7	
21.6	201.7	
21.7	—	
a)	201.7.9.1	

Table HH.1 *(continued)*

Essential principle of ISO 16142-1:2016[7]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
b)	201.7	
d)	201.7.2.17.101, 201.7.9.2.1.102 b)	
g)	201.7	
h)	201.7	
i)	201.7.9.2.2	
k)	201.7.9.2.9.101.2 g), 201.7.9.2.9.101.2 h), 201.7.9.2.9.101.2 j), 201.7.9.2.14.101, 201.102	
l)	201.7, 201.7.9.2.13.101	
n)	201.7.9.2.2	
p)	201.7.9.2.12, 201.11.6.6, 211	
q)	201.7	
21.8	201.7	
21.9	211	
a)	211	
b)	211	
c)	211	
d)	211	
e)	211	
f)	211	

Annex II
(informative)

Terminology — Alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP)[4] and the IEC Electropedia[5] provide access to many of these terms and definitions.

Term	Source
ACCESSIBLE PART	IEC 60601–1:2005+AMD1:2012, 3.2
ACCESSORY	IEC 60601-1:2005+AMD1:2012, 3.3
ACCOMPANYING DOCUMENT	IEC 60601-1:2005+AMD1:2012, 3.4
ACTIVE HEAT AND MOISTURE EXCHANGER	201.3.201
ACTIVE HME	201.3.201
AIRWAY PRESSURE (P_{aw})	201.3.202
ALARM CONDITION	IEC 60601–1:2005+AMD1:2012, 3.141
ALARM LIMIT	IEC 60601–1-8:2006, 3.3
ALARM PAUSED	IEC 60601–1-8:2005, 3.5
ALARM SIGNAL	IEC 60601–1-8:2005, 3.9
ALARM SYSTEM	IEC 60601–1-8:2006, 3.11
APPLIED PART	IEC 60601–1:2005, 3.8
AUDIO PAUSED	IEC 60601–1-8:2006, 3.13
BASIC SAFETY	IEC 60601–1:2005, 3.10
BODY TEMPERATURE PRESSURE, SATURATED	201.3.203
BREATHING SYSTEM	ISO 4135:2001, 4.1.1[1]
BREATHING SYSTEM FILTER	ISO 23328-2:2002, 3.1[9]
BREATHING TUBE	ISO 4135:2001, 4.1.2[1]
BTPS	201.3.203
CLEARLY LEGIBLE	IEC 60601–1:2005+AMD1:2012, 3.15
[a] To be published.	

[4] Available at https://www.iso.org/obp/ui/#home.

[5] Available at http://www.electropedia.org.

Term	Source
CONTINUOUS OPERATION	IEC 60601–1:2005, 3.18
DELIVERED GAS TEMPERATURE	201.3.204
DISTRIBUTED ALARM SYSTEM	IEC 60601–1-8:2006, 3.17
ENCLOSURE	IEC 60601–1:2005, 3.26
ESSENTIAL PERFORMANCE	IEC 60601–1:2005+AMD1:2012, 3.27
F-TYPE APPLIED PART	IEC 60601–1:2005, 3.29
FUNCTIONAL CONNECTION	IEC 60601–1:2005, 3.33
FLOW-DIRECTION-SENSITIVE COMPONENT	201.3.205
GAS PATHWAY	ISO 18562-1:2016[a], 3.5
HARM	IEC 60601–1:2005, 3.38
HAZARD	IEC 60601–1:2005+AMD1:2012, 3.39
HAZARDOUS SITUATION	IEC 60601–1:2005+AMD1:2012, 3.40
HEAT AND MOISTURE EXCHANGER	ISO 9360-1:2000, 3.1[5]
HEATED BREATHING TUBE CONTROLLER	201.3.206
HME	ISO 9360-1:2000, 3.1[5]
HOME HEALTHCARE ENVIRONMENT	IEC 60601–1-11:2015, 3.1
HUMIDIFICATION CHAMBER	201.3.207
HUMIDIFICATION OUTPUT	201.3.208
HUMIDIFIER	201.3.209
IMMUNITY	IEC 60601–1-2:2014, 3.8
INTENDED USE	IEC 60601–1:2005+AMD1:2012, 3.44
INTERNAL ELECTRICAL POWER SOURCE	IEC 60601–1:2005, 3.45
LAY	IEC 60601–1-11:2015, 3.2
LEAKAGE CURRENT	IEC 60601–1:2005, 3.47
LIQUID CONTAINER	201.3.210
LIQUID RESERVOIR	201.3.211
MANUFACTURER	IEC 60601–1:2005+AMD1:2012, 3.55
MAXIMUM LIMITED PRESSURE ($P_{\text{LIM max}}$)	201.3.212
MAXIMUM OPERATING PRESSURE	201.3.213
ME EQUIPMENT	IEC 60601–1:2005, 3.63
ME SYSTEM	IEC 60601–1:2005, 3.64
[a] To be published.	

Term	Source
MEDICAL ELECTRICAL EQUIPMENT	IEC 60601–1:2005, 3.63
MEDICAL ELECTRICAL SYSTEM	IEC 60601–1:2005, 3.64
MEANS OF PROTECTION (MOP)	IEC 60601–1:2005, 3.60
MEASURED GAS TEMPERATURE	201.3.214
MEDICAL GAS PIPELINE SYSTEM	ISO 7396-1:2016, 3.29
MEDIUM PRIORITY	IEC 60601–1-8:2006, 3.28
MOBILE	IEC 60601–1:2005+AMD1:2012, 3.65
MODEL OR TYPE REFERENCE	IEC 60601–1:2005, 3.66
MONITORING EQUIPMENT	201.3.215
NOMINAL (VALUE)	IEC 60601–1:2005, 3.69
NORMAL CONDITION	IEC 60601–1:2005, 3.70
NORMAL USE	IEC 60601–1:2005+AMD1:2012, 3.71
OPERATOR	IEC 60601–1:2005, 3.73
PATIENT	IEC 60601–1:2005+AMD1:2012, 3.76
PATIENT CONNECTION	IEC 60601–1:2005, 3.78
PATIENT-CONNECTION PORT	201.3.216
PATIENT LEAKAGE CURRENT	IEC 60601–1:2005, 3.80
PORTABLE	IEC 60601–1:2005+AMD1:2012, 3.85
PEMS	IEC 60601–1:2005, 3.90
PESS	IEC 60601–1:2005, 3.90
PRIMARY OPERATING FUNCTION	IEC 62366–1:2015, 3.13[18]
PROCEDURE	IEC 60601–1:2005+AMD1:2012, 3.88
PROCESS	IEC 60601–1:2005+AMD1:2012, 3.89
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM	IEC 60601–1:2005, 3.90
PROGRAMMABLE ELECTRONIC SUBSYSTEM	IEC 60601–1:2005, 3.90
PROTECTION DEVICE	201.3.217
RATED (VALUE)	IEC 60601–1:2005, 3.97
RELATIVE HUMIDITY	201.3.218
RESIDUAL RISK	IEC 60601–1:2005+AMD1:2012, 3.100
RESPONSIBLE ORGANIZATION	IEC 60601–1:2005, 3.101
RISK	IEC 60601–1:2005+AMD1:2012, 3.102
[a] To be published.	

Term	Source
RISK CONTROL	IEC 60601–1:2005+AMD1:2012, 3.105
RISK MANAGEMENT	IEC 60601–1:2005+AMD1:2012, 3.107
RISK MANAGEMENT FILE	IEC 60601–1:2005+AMD1:2012, 3.108
SET TEMPERATURE	201.3.219
SINGLE FAULT CONDITION	IEC 60601–1:2005+AMD1:2012, 3.116
STANDARD TEMPERATURE AND PRESSURE, DRY	201.3.220
STPD	201.3.220
TOOL	IEC 60601–1:2005, 3.127
TRANSIT-OPERABLE	IEC 60601–1-11:2015, 3.4
USABILITY	IEC 62366–1:2015, 3.16[18]
USABILITY ENGINEERING FILE	IEC 62366–1:2015, 3.18[18]
USE SPECIFICATION	IEC 62366–1:2015, 3.23[18]
VALIDATION (VALIDATED)	201.3.221
VERIFICATION (VERIFIED)	IEC 60601–1:2005+AMD1:2012, 3.138
[a] To be published.	

Bibliography

[1] ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

[2] ISO 8185:2007, *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems*

[3] ISO 7000:2014, *Graphical symbols for use on equipment — Registered symbols*

[4] ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

[5] ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

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